



EUROPEAN COMMISSION
DG Competition

***Case M.7982 - ABBOTT
LABORATORIES /
ALERE***

Only the English text is available and authentic.

**REGULATION (EC) No 139/2004
MERGER PROCEDURE**

Article 6(1)(b) in conjunction with Art 6(2)
Date: 25/01/2017

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Brussels, 25.01.2017
C(2017) 482 final

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus [...]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

**Subject: Case M.7982 - ABBOTT LABORATORIES / ALERE
Commission decision pursuant to Article 6(1)(b) in conjunction with
Article 6(2) of Council Regulation No 139/2004¹ and Article 57 of the
Agreement on the European Economic Area²**

Dear Sir or Madam,

- (1) On 29 November 2016, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which the undertaking Abbott Laboratories ("Abbott", USA) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of the undertaking Alere Inc. ("Alere", USA) by way of purchase of shares.³ Abbott and Alere are collectively referred to as "the Parties".

1. THE PARTIES

- (2) Abbott is a global health care company that researches, develops, manufactures and sells a diversified range of health care products, including diagnostic products. Diagnostic products sold by Abbott include a broad line of diagnostics systems and tests manufactured, marketed and sold worldwide, principally to blood banks, hospitals, commercial laboratories and clinics.

¹ OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation'). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ('TFEU') has introduced certain changes, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this decision.

² OJ L 1, 3.1.1994, p. 3 (the 'EEA Agreement').

³ Publication in the Official Journal of the European Union No C455, 6.12.2016, p. 6

- (3) Alere produces professional diagnostic solutions for infectious diseases, cardiometabolic diseases and toxicology, with a focus on near the patient, point-of-care testing.

2. THE OPERATION AND THE CONCENTRATION

- (4) On 30 January 2016, Abbott and Alere signed a definitive agreement for Abbott to acquire all the issued and outstanding shares of Alere. The transaction has been approved by the boards of directors of Alere and Abbott, as well as by Alere's shareholders.
- (5) As a result of the Proposed Transaction, Abbott will acquire sole control over Alere.
- (6) The Transaction therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

3. EU DIMENSION

- (7) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million.⁴ Each of them has an EU-wide turnover in excess of EUR 250 million, but each does not achieve more than two-thirds of its aggregate EU-wide turnover within one and the same Member State. The notified operation therefore has an EU dimension.

4. COMPETITIVE ASSESSMENT

4.1. Introduction

4.1.1. General description of the IVD sector

- (8) The main impact of the Transaction is in the area of in vitro diagnostics systems ("IVD systems"). IVD systems comprise analysers, reagents and accessories for the purpose of conducting clinical tests outside the human or animal body using blood, urine or other samples.⁵
- (9) Analysers are measurement instruments designated for the automated operation of several kinds of specific analyses (tests) to diagnose a medical problem or condition. They can be either automated instruments with high throughput rates ('large volume analysers' or 'laboratory analysers') used in hospitals' core laboratories and blood banks, or point-of-care analysers, which are smaller and can be taken nearer to the patient.
- (10) Within point-of-care analysers, a distinction is usefully made between sophisticated analysers which can be run/used exclusively by health care professionals in a medical environment (referred as "POC" in this Decision) on the one hand; and analysers which can also be used by the patient himself outside of a medical

⁴ Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.4.2008, p. 1).

⁵ As explained later in the present Decision, IVD systems are used in human medicine but can also be used in the veterinary sector.

environment (referred to as "rapid tests" or "self-testing" in this Decision) on the other hand.⁶

- (11) Reagents (also called assays) are the products necessary to carry the specific analyses (tests). Reagents are consumable solutions of specific biologic or chemical substances that react with target substances in samples (such as blood, tissue or urine) to produce a result that can be measured or seen.
- (12) In laboratory analysers, reagents are supplied in vials, or bottles on a stand-alone packaging basis. POC analysers work with single use cartridges that often cover a range of tests ("multi-test panel cartridges"), but it can also happen that a cartridge runs a single test ("single-test panel cartridges").
- (13) Finally, accessories are ancillary products needed to perform the diagnostic testing and ensure the smooth functioning of the entire system. Among accessories, calibrators, standards and controls serve for regular adjustments of the measuring instruments and quality control runs.

4.1.2. *Main activities of the Parties*

- (14) Abbott is among the largest players in laboratory IVD systems, in particular with its analysers ARCHITECT or PRISM used in core laboratories and blood banks. In POC segment, Abbott has a limited offering of devices, the i-STAT and various glucose meters for diabetes testing (e.g. the Abbott Freestyle Pro System).
- (15) Alere's activities focus on the point-of-care IVD segment, offering POC systems and rapid tests. Alere does not market own branded glucose meters for POC diabetes testing.
- (16) The main overlap between the Parties' activities concern the POC segment where Abbott is active with its i-STAT system and Alere essentially with its EPOC and Triage systems. A large part of this Decision is therefore dedicated to the POC segment.⁷
- (17) In the laboratory segment, the overlaps between the Parties' activities (mainly Abbott's direct activities and Alere re-selling activities) leads to some affected markets which are analysed in the present Decision.
- (18) In the area of rapid tests, the overlaps of the Parties' activities are limited to glucose self-testing systems, where Abbott has a direct presence and Alere is re-selling third

⁶ Rapid tests are primarily manual tests for several applications (e.g. blood glucose monitoring, pregnancy and ovulation, drug monitoring, anticoagulant and HIV testing), carried out by patients themselves or by doctors. No sophisticated separate analyser is necessary.

⁷ The Parties' activities also overlap in point-of-care coagulation testing systems. However, their activities are mainly complementary with Alere being active with its main self-testing (fingerstick device) INRatio device, while Abbott is only providing one coagulation test as an add-on to its i-STAT analyser. Alere's Triage also offers some add-on coagulation tests, but different from the one available in the i-STAT. Finally, Alere INRatio is currently being discontinued following input from the US Food and Drug Administration (FDA), a prohibition decision in France as well as previous recalls. Therefore, this market will not be further assessed in this Decision.

party products. However, the Transaction does not give rise to affected markets⁸ and this area will therefore not be assessed further in this Decision.

4.2. Market definitions

4.2.1. Product markets

4.2.1.1. Distinction between laboratory and Point-of-Care

- (19) Laboratory analysers are high-throughput machines for core laboratory applications with a broad test menu, while POC analysers are being used in a near-the-patient setting for time-sensitive tests. POC analysers are characterised by small size, a limited test menu, fast results and often operated outside the core or central laboratory.
- (20) In previous decisions,⁹ the Commission considered a possible distinction between (i) laboratory systems and (ii) POC systems, ultimately leaving the relevant product market open. In another decision, the Commission considered that rapid tests form a separate product market based on differences in customers, distribution channels and competitive conditions.¹⁰

The Notifying Party's view

- (21) The Notifying Party acknowledges that laboratory and POC analysers have different features, with Abbott being focused on laboratory systems while Alere is mainly active in POC systems. However, the Notifying Party considers that it can be left open whether laboratory and POC systems belong to separate product markets.

The Commission's assessment

- (22) The results of the market investigation generally indicated that IVD POC analysers are not considered as interchangeable with those IVD laboratory analysers that perform the same tests.¹¹ IVD POC analysers have different features and therefore do not address the same customers' needs.¹²
- (23) While IVD POC tests are more expensive and unsuitable to achieve high throughput, these devices provide faster results. One customer indicated that POC analysers serve "*urgent on the spot needs and support instant decision making where speed is essential*".¹³ This is particularly true for some hospital services, for instance neonatal or adult intensive care, emergency units or "*high-impact anaesthesia services*",¹⁴ in

⁸ Based on the number of placed units or sold reagents (GIVD code 11.70.01.01).

⁹ See M.4569, *GE/Abbott Diagnostics Division*, 24/04/2007, paras 18 and 20; M.4865, *Siemens/ Dade Behring*, 25/10/2007, paras 28 and 29; M.6175, *Danaher/ Beckman Coulter*, 16/06/2011, paras 16 and 17.

¹⁰ Case IV/M.950, *Hoffman La Roche/Boehringer Mannheim*, 04/02/1998, para 35.

¹¹ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 12 and 12.1 and responses to Questionnaire Q1 to Competitors of 29 November 2016, question 8

¹² Responses to Questionnaire Q1 to Competitors of 29 November 2016, question 8.1

¹³ Response of to Questionnaire Q2 to Customers of 29 November 2016, question 12.1. See also response of to Questionnaire Q2 to Customers of 29 November 2016, question 5

¹⁴ Response of to Questionnaire Q2 to Customers of 29 November 2016, question question 5

which quick results are needed, but also for extra-hospital locations, for instance in ambulances.¹⁵

- (24) The results of the market investigation also indicated that there is an increasing need for POC systems, since they address urgent patients' needs in the context of a growing trend towards laboratories' centralisation and concentration.¹⁶
- (25) In view of the above and in particular the absence of substitutability from the demand side, for the purpose of assessing this Transaction, the Commission concludes that there are separate product markets for laboratory and POC systems.

4.2.1.2. IVD systems versus analysers and reagents

- (26) In previous decisions related to the IVD sector,¹⁷ the Commission considered whether competition takes place at the level of systems (including the analysers and all reagents used in these analysers) or whether competition should be assessed separately for analysers on the one hand and for reagents on the other hand.
- (27) The Commission generally found the distinction between analysers and reagents to be unnecessary since IVD analysers are often proprietary or "technically closed", meaning that analysers of a certain manufacturer only perform tests through reagents of that same manufacturer.

The Notifying Party's view

- (28) The Notifying Party considers that the relevant product market consists in IVD systems, as opposed to distinct markets for analysers and reagents. In part, this is because customers typically do not purchase these products separately but rather buy them as part of a single system.

The Commission's assessment

- (29) The results of the market investigation generally confirmed that customers purchase an IVD system comprising an analyser and all related reagents.¹⁸ This is particularly true in the POC space, where analysers are typically closed systems, so that customers need to purchase both the analyser and the reagents from the same supplier. The analysers offered by the Parties are closed systems.
- (30) In the laboratory space however, while Abbott supplies both analysers and reagents used in its Architect branded analysers, Alere's activities generally focus either in supplying analysers or supplying reagents, depending on the markets concerned.
- (31) Therefore, for the purpose of this Decision, the Commission concludes that the relevant POC product markets are at the level of IVD systems. Conversely, as

¹⁵ Response of to Questionnaire Q2 to Customers of 29 November 2016, question 5

¹⁶ Responses of to Questionnaire Q2 to Customers of 29 November 2016, question 5

¹⁷ See namely M.4321, *Siemens/ Bayer Diagnostics*, 31/10/2006, para 23; COMP/M.4569 *GE/Abbott Diagnostics Division*, 24/04/2007, para 19; M.4865, *Siemens / Dade Behring*, 25/10/2007, para 27; M.6175, *Danaher / Beckman Coulter*, 16/06/2011, para 13; COMP/M.7787, *Panasonic Healthcare/ Bayer's Diabetes Care Business*, 23/11/2015, para 22.

¹⁸ Agreed minutes of conference calls held with a competitor dated 11 July 2016, para 13 and with another competitor dated 15 July 2016, para 16: "*The usual mechanism in the EEA for a contract with a hospital, following a tender, is to provide a "system" for a given application, with a contract of several years.*"

regards the laboratory markets, it can be left open whether analysers and reagents belong to separate or single product markets, since under any plausible of the abovementioned alternative market definitions (for systems overall, analysers only or reagents only) in the laboratory space, the conclusion of the Commission as to the compatibility of the Transaction with the internal market will remain unchanged.

4.2.1.3. **Distinctions within POC IVD systems**

The Notifying Party's view

- (32) The Notifying Party considers that, if POC IVD systems are found to belong to a separate market from laboratory IVD systems, the relevant product market of POC systems should not be further segmented.
- (33) The Notifying Party considers that POC analysers for use by healthcare professionals are primarily applied in near-patient settings where the timely availability of tests' results is of major importance, such as in surgical suites, emergency departments and critical care areas. A broad portfolio of tests is required in that environment, the most common test panels being blood gas/other chemistries and cardiac markers.
- (34) The Notifying Party however considers that there is no need to segment between (i) benchtop versus handheld systems and analysers since both provide simple and fast test results in a small footprint machine or (ii) blood gas/other chemistries versus cardiac markers since analysers generally provide a wide and comprehensive range of test panels.
- (35) The Notifying Party finally considers that there is no need to segment between single-test panel and multi-test panel cartridges for either blood gas and cardiac markers testing. These different cartridges options are considered to be a design and market offering choice of the manufacturers which is based on customers' need and market demand.

The Commission's assessment

Distinction by test panels or specific tests

- (36) In previous decisions,¹⁹ the Commission considered a possible distinction in the IVD markets by (i) thematic panels or (ii) by specific reagents.
- (37) At the level of testing panels in POC, a distinction can be made between blood gas and cardiac markers testing.
- (38) Blood gases are vital parameters (such as pH, pO₂ and pCO₂) that must be closely monitored for patients admitted into critical care, undergoing prolonged anaesthesia or when a patient is on oxygen. Blood gas analysis is commonly combined with testing for other chemistries such as electrolytes and metabolites and for haemoglobin status.

¹⁹ See namely M.4321, *Siemens/ Bayer Diagnostics*, 31/10/2006, para 17; M.4569, *GE/ Abbott Diagnostics Division*, 24/04/2007, para 19; M.4865, *Siemens/ Dade Behring*, 25/10/2007, para 23; M.6293, *Thermo Fisher/Phadia*, 18/08/2011, para 17.

- (39) The results of the market investigation show that customers typically purchase a blood gas system, performing the whole range of blood gas tests.²⁰ Indeed, systems usually cover all the tests mentioned above, that are key for the diagnosis of patients admitted to critical care. One customer indicated that the nature of the parameters and the ability to test more than one parameter on the device is a determining factor in choosing a POC analyser because "*the approach of using an analyser is not the same if it is a single test analyser or if the device can process multi test cartridges*".²¹ To address this demand²², almost all blood gas manufacturers offer a range of multi-panel test cartridges, enabling the measurement of blood gases, specific ions and/or specific metabolites.
- (40) Cardiac markers are biomarkers measured to evaluate heart functions, that is to either diagnose a cardiac event or to evaluate the risk of cardiac event occurring.
- (41) To diagnose a cardiac event, the main markers used are creatinine kinase MB (CKMB), Troponin and myoglobin, with Troponin being the preferred test to detect a suspected heart attack. To evaluate the risk of cardiac event occurring, the main markers used are B-type natriuretic peptide (BNP) and N-terminal pro b-type natriuretic peptide (NT-proBNP). BNP and NT-proBNP are primarily used to help detect, diagnose and evaluate the existence or severity of a heart failure.²³
- (42) In general, in cardiac marker testing, one or two tests are needed for a given diagnostic. The results of the market investigation showed that doctors generally use specific tests, such as Troponin, BNP or NT-proBNP markers. The possibility to carry out these specific tests generally drives the purchasing decision.²⁴ Manufacturers, such as Abbott, therefore supply single-test cartridges.
- (43) In view of the above, for the purpose of assessing this Transaction, the Commission concludes that there are separate product markets for POC IVD systems for blood gas, cardiac markers testing, and leaves open whether there should be a distinction between (i) multi-use and single use cartridges and (ii) for specific tests or combination thereof.

Distinction between portable and non-portable POC analysers

- (44) In POC markets, analysers are differentiated based on several characteristics, including tests menu (see above on distinction by tests panels or specific tests), throughput (number of tests which can be performed), cost per test, turnaround time (duration to obtain the results from the sample), and portability.
- (45) The results of the market investigation show that, similarly to the distinction between laboratory and POC analysers, benchtop (immobile) POC analysers and

²⁰ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 19

²¹ Agreed minutes of a conference call held with a customer dated 19 October 2016, para 9

²² Agreed minutes of a conference call held with a competitor, para 7: "*The customers are increasingly interested in buying multi-cartridge systems which allow them to test the relevant parameters for a certain disease state (following the typical prescription of a medical doctor) based on one blood sample.*"

²³ BNP helps to detect heart failure, so as to be able to evaluate cardiac event risks.

²⁴ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 20.2

handheld (bedside) POC analysers address different customers' needs even if they perform the same tests.²⁵

- (46) The results of the market investigation show that portable and non-portable analysers (with a spectrum from immobile benchtop to fully portable handheld) are not interchangeable in terms of test volume (benchtop devices having a much higher throughput rate), turnaround time (portable devices usually providing faster results) and price range (portable device being generally more expensive in terms of costs per test).²⁶
- (47) The absence of substitution between benchtop and handheld analysers has been highlighted by several customers and competitors in particular for blood gas testing. One key opinion leader in the area of blood gas indicated that benchtops have to be considered as an *"intermediate category of IVD products"* which are not perceived *"as an alternative [...] to handheld solutions"* because *"they do not have the advantage to be portable devices which can be brought at the patient's bedside"*.²⁷ The major difference is that while with benchtop devices the blood sample is taken to the device, with handheld analysers, the device is taken near the patient and the test performed on the spot.²⁸
- (48) Portability appears to be a determining factor depending on the role of the healthcare professional in emergency and maternity departments.²⁹ More specifically, having bedside devices is critical in neonatal units, perioperative units and ambulatory services.³⁰ Some customers indicated having done in the past calls for proposals/tenders for handheld analysers only³¹ or having different suppliers for POC blood gas testing to have both benchtop and handheld devices.³²
- (49) In addition, customers consider that portable devices limit the risk of results confusion but also *"infection (because there is less handling) and unnecessary*

²⁵ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 14.1, namely response of a customer: *"Both deliver very much the same results - they do so by following different processes but are interchangeable when it comes to the end result (consistency with results generally, same quality but used or different purposes)"* but also of another customer: *"It depends on the clinical need and location of required POC test."*

²⁶ Responses to Questionnaire Q2 to Customers of 29 November 2016, questions 13, 14 and 15

²⁷ Agreed minutes of a conference call held with a Key Opinion Leader dated 26 October 2016, para 8

²⁸ Agreed minutes of conference calls held with competitors dated 11 and 29 July 2016

²⁹ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 14.1, see namely the reply of a customer: *"It will depend on the role of healthcare professionals within such environments and whether real time patient interaction (facilitated by held analysers) will offer perceived benefits."*

³⁰ Agreed minutes of a conference call held with a customer dated 19 October 2016, para 11: *"portability and throughput rate features may be determining factors for emergency and resuscitation services, maternity services and emergency medical assistance services (known in France as SAMU)";* See also responses to Questionnaire Q2 to Customers of 29 November 2016, questions 13, 14, 14.1 and 17, see namely the reply of a customer to question 14.1: *"(...) when in need for use in mobile teams such as for example in ambulances"*.

³¹ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 16, namely the reply of a customer: *"my organisation considered the handheld feature of an IVD POC analyser as a key criterion in procurement as necessary in a clinical contest very close to patients as home care, community hospitals etc. This was specified in the criterion in tenders where was requested a class of handheld analysers";* see also the reply of another customer: *"whether a POC IVD system is hand-held or benchtop is always a criterion. this is included in the purchase procedure"*.

³² Responses to Questionnaire Q2 to Customers of 29 November 2016, question 23.1

commuting between the ward and a patient's room".³³ They are also considered to be more user-friendly instruments for doctors and nurses. One customer highlighted that it had tried to switch from handheld analysers to benchtop solutions that perform equivalent analyses at a lower cost but that the proposed switch encountered strong opposition from hospital personnel, "for whom a handheld solution represents a consistent advantage for their daily work".³⁴ Handheld analysers can also be seen as more reliable by some customers as they require "cartridges' quality control and calibration at each use, whereas benchtops are only calibrated each 100 to 200 tests".³⁵

- (50) The distinction between benchtop and handheld devices is also confirmed by the Parties' internal documents in particular on the competitive landscape for blood gas testing. For instance, in a document on Alere's possible future strategy for its blood gas EPOC analyser, a distinction is clearly made between handheld bedside testing analysers (having a turnaround time of a few minutes) and benchtop analysers (having a turnaround time of approximately 15 to 30 minutes), acknowledging that EPOC [Confidential excerpt from Parties' internal document].³⁶
- (51) In view of the above, the distinction between portable and non-portable POC analysers appears relevant in particular for blood gas POC testing. However, for assessing the present decision, this distinction can be left open since under any of the abovementioned alternative market definitions (namely for all POC systems or for handheld POC systems only), the conclusion of the Commission as to the compatibility of the Transaction with the internal market will remain unchanged.

Distinction between human and veterinary uses

- (52) IVD systems can be used in human health but also in the veterinary space. More specifically, both Abbott and Alere manufacture analysers and reagents for animal blood gas testing.
- (53) The results of the market investigation showed that a distinction can be made between POC IVD blood gas systems for human medicine and veterinary uses. If the analysers and the reagents are generally the same, the reference values for performing the test differ between humans and other animals. To avoid misuse, the analysers aimed for animal testing can only process reagents aimed for animal testing as the veterinary and human cartridges use different barcodes.³⁷ In addition, POC IVD blood gas systems for human medicine and veterinary use are characterised by a different customer base.

³³ See also agreed minutes of a conference call held with a customer dated 3 November 2016, para 13: "As regards POC devices, [...] considers that benchtops are less advantageous than handhelds for doctors and nurses. First, they require much more manipulation than handhelds".

³⁴ Agreed minutes of a conference call held with a customer dated 27 October 2016, para 10

³⁵ Agreed minutes of a conference call held with a customer dated November 2016, para 13; See also response of a customer to Questionnaire Q2 to Customers of 29 November 2016, question 15.2: "Benchtop analysers require regular maintenance at an extra cost. This maintenance has to be done at regular intervals, often throughout the working day at times when the analyser is in demand thereby delaying clinical work. If an analyser breaks during the night there is generally no immediate help available and an alternative way to process samples will have to be found. Handheld devices do not have to be taken out of service for regular maintenance and if they stop working can simply be replaced with another device without interrupting clinical workflow".

³⁶ "Epic Market Insight", Alere, 12 July 2015, p 1756 (Annex 22.2.47).

³⁷ Agreed minutes of a conference call with a customer dated 21 December 2016, para 7

- (54) The results of the market investigation revealed that the market features between human and veterinary uses for POC blood gas testing are broadly similar, as regards namely the price range, the calibration process, the throughput rate, with the handheld characteristic being also key for veterinaries.
- (55) The criterion of portability appears to be crucial in emergency and critical care veterinarian units,³⁸ during surgery or in case of ambulatory practices (especially when performing IVD tests on horses or dogs³⁹).
- (56) In view of the above, for the purpose of assessing this Transaction, the Commission concludes that there are separate product markets for POC IVD blood gas systems for human and animal health, with a possible segmentation between benchtop and handheld analysers which can be left open since under all above-mentioned plausible alternative market definitions, namely for both human use and veterinary use separately all POC blood gas systems or handheld POC blood gas systems only, the conclusion of the Commission as to the compatibility of the Transaction with the internal market will remain unchanged.

4.2.1.4. General distinction within IVD laboratory

The Notifying Party's view

- (57) The Notifying Party considers that a distinction can be made between six main categories:
- (i) Clinical chemistry includes diagnostics that are mainly used to test glucose, cholesterol, sodium and other substances found in large concentrations in the blood stream;
 - (ii) Immuno-chemistry involves the use of targeted antibodies to identify and test enzymes, drugs, hormones and other substances found in relatively small concentrations in samples in order to diagnose a variety of medical problems such as cancer, HIV and thyroid problems;
 - (iii) Haematology/haemostasis/Immunohaematology/histology/cytology includes tests concerning the blood itself, especially cellular elements and certain functions of proteins such as coagulation and fibrinolysis;
 - (iv) Microbiology culture includes the culturing of samples and the identification of specific organisms through selective and chromatographic media;
 - (v) Infectious diseases includes all tests performed in connection with certain diseases caused by bacterial or viral infection; and
 - (vi) Genetic testing includes testing products classified into two main categories depending on whether the gene or chromosome alterations tested for are inborn (various disorders or acquired (mainly cancer related)).

³⁸ Agreed minutes of a conference call held with a Key Opinion Leader in the field of blood gas in the veterinary space dated 21 December 2016, para 9

³⁹ Responses to Questionnaire R3 to Customers in the veterinary space of 5 January 2017, question 1; See also agreed minutes of a conference call held with a customer dated 21 December 2016

- (58) The Notifying Party considers that within these six main categories, distinction can be made by thematic panels or even specific tests.
- (59) The Notifying Party considers however that the product market definition can be left open.

The Commission's assessment

- (60) In previous decisions,⁴⁰ the Commission considered within laboratory IVD systems a possible distinction between Clinical Chemistry, Immunochemistry, Haematology/Histology, Microbiology, Infectious Immunology and Genetic Testing. The Commission also assessed segments within each category by thematic panels or even looking at specific tests.⁴¹ The Commission also assessed a possible market comprising all clinical and immunochemistry IVD systems, considering the strong interest of customers in using integrated testing systems which perform both clinical chemistry and immunochemistry tests on the same analyser, and which rationalizes their testing procedures, increases efficiency and reduces their costs.⁴²
- (61) For the purpose of this Decision, the Commission agrees with the general distinctions described above between the six main IVD categories, with a possible convergence between clinical and immunochemistry, but also with possible segments by tests panels or specific tests. The precise product markets definition in the laboratory IVD space can be left open since under all above-mentioned plausible alternatives, namely distinction by IVD categories, thematic panels or specific tests as well as IVD clinical and immunochemistry together, the conclusion of the Commission as to the compatibility of the Transaction with the internal market will remain unchanged.

4.2.2. *Geographic markets*

- (62) In previous decisions, the Commission has considered IVD markets to be national as customers (central laboratories, blood banks and hospitals) source products and after-sales services from within the country where they are located.⁴³ It was found that customers tend to buy their instruments and reagents within their country because of the need for rapid and reliable service to ensure continuous availability of these products, the existence of national reimbursement schemes, and in view of price differences.⁴⁴ However, the Commission has also acknowledged that the relevant geographic market may be increasingly EEA-wide in scope as all major providers of IVD systems are active worldwide and supply the same equipment and reagents in identical form, with identical designs and labelling throughout the

⁴⁰ M.4569, *GE/ Abbott Solvay Diagnostics Division*, 24/04/2007, para 17; M.4788, *Rozier/ BHS*, 21/08/2007, para 12; M.6175, *Danaher/ Beckman Coulter*, 16/06/2011, para 9; M.6293, *Thermo Fisher/ Phadia*, 18/08/2011, para 8; M.7787, *Panasonic Healthcare/ Bayer's Diabetes Care Business*, 23/11/2015, para 17.

⁴¹ See namely M.4321, *Siemens/ Bayer Diagnostics*, 31/10/2006, para 17; M.4569, *GE/ Abbott Diagnostics Division*, 24/04/2007, para 19; M.4865, *Siemens/ Dade Behring*, 25/10/2007, para 23; M.6293, *Thermo Fisher/Phadia*, 18/08/2011, para 17.

⁴² M.4865, *Siemens/ Dade Behring*, 25/10/2007, paras 12-14

⁴³ M.4865, *Siemens/ Dade Behring*, 25/10/2007, para 34; M.6293, *Thermo Fisher/ Phadia*, 18/08/2011, paras 21-22

⁴⁴ M.4865, *Siemens/ Dade Behring*, 25/10/2007, paras 34-36

EEA.⁴⁵ This holds in particular for smaller EEA Contracting Parties where fewer producers of IVD systems are directly represented, and customers may therefore be more inclined than in other EEA Contracting Parties to directly purchase the products concerned abroad.⁴⁶

- (63) The Notifying Party considers that the exact scope of the geographic market can be left open since the Transaction does not raise any concerns at either the national or the EEA level.
- (64) Some elements of the market investigation point toward an increasingly broader than national scope of the IVD market as the most important IVD suppliers are active on a worldwide basis and formal tenders often reach the European thresholds, opening the selection to local, national but also multinational companies and suppliers.⁴⁷ However, the market investigation has to a large extent confirmed that suppliers either use national third party distributors or reach directly end-customers through national sales force to respond to the need of local customers,⁴⁸ which is an indicator pointing towards national markets. A majority of respondents also confirmed the importance of having distribution channels and sales force at national level⁴⁹ and complying to national regulation (such as translations requirements), even if the nature of products does not differ within the EEA due to regulatory requirements.⁵⁰ Some respondents also indicated that price differences exist between national markets due to differences in reimbursement prices across the EEA.⁵¹
- (65) In view of the above, the Commission concludes that relevant geographic markets for the IVD markets considered in this Decision are national.

4.3. Competitive assessment

4.3.1. Methodology for the calculation of market shares

- (66) To assess the Parties' positions on the IVD market, market shares have been estimated both in terms of reagent sales and in terms of the installed base of analysers.

Market shares based on reagent sales

- (67) In the EEA, the European Diagnostics Manufacturers' Association ("EDMA") created a scheme, known as the Global IVD ("GIVD") classification, which is a

⁴⁵ M.4569, *GE/Abbott Diagnostics Division*, 24/04/2007, para 21

⁴⁶ M. 4865, *Siemens/Dade Behring*, 25/10/2007, para 36

⁴⁷ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 4

⁴⁸ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 4.1 customers and responses to Questionnaire Q1 to Competitors of 29 November 2016, question 4

⁴⁹ Responses to Questionnaire Q1 to Competitors of 29 November 2016, question 7

⁵⁰ Directive 98/79 of the European Parliament and of the Council of 27 October 1998 on in vitro medical devices, ("the IVD Directive"), (OJ L 331, 7.12.1998, p.1) sets out the regulatory requirements that such devices must meet before they can be put on the market in the EU, regardless of whether they are manufactured in the EU or elsewhere.

⁵¹ Responses to Questionnaire Q1 to Competitors of 29 November 2016, question 7

numerical coding system developed to support the collection and analysis of market statistics.⁵²

- (68) GIVD classifies IVD reagents into six main categories, corresponding to the categories reported in paragraph (60) (level 1). Within each of these first levels, the GIVD proposes a second level of classification based on thematic panels of tests (level 2). There is then a third level of classification based on more specific types of diseases and assays/reagents (level 3) and finally a fourth level of classification, e.g., based on a specific test for a specific condition (level 4). The distinction between the laboratory and the POC segments is also reflected in the GIVD taxonomy at level 2, which separates POC reagents from reagents used on laboratory analysers into specific codes.
- (69) The results of the market investigation show that the GIVD classification is a tool widely used in the diagnostic industry, in particular in the laboratory area, and is generally considered as reliable for reagents sale. However, the results of the market investigation also indicate that this database is less reliable when relating to sales of instruments⁵³ and to the narrower segment of POC reagents, where important competitors do not report⁵⁴.
- (70) For the evaluation of the Parties' market shares, the Parties have provided best estimates of their reagents' sales, developed on the basis of GIVD data. No data could be provided for the Parties' competitors since the individual statistics remain confidential to each participant. The Notifying Party considers that their reagents' sales reflect their current market position both in the laboratory and POC systems.
- (71) Market shares based on reagent sales constitute a proxy to evaluate the Parties' market position because their POC systems are closed systems, so that customers need to purchase both analyser and corresponding reagents from the Parties. However, as indicated above, the GIVD data have limitations in particular for the POC reagents' sales⁵⁵. In addition, since POC analysers may have very different throughput,⁵⁶ market shares based on reagent sales may not accurately reflect the Parties' market position in the market for POC systems. The Parties therefore also provided data including their best estimates of their market shares based on their current installed base.

⁵² In the EEA, there are 13 national diagnostic manufacturers associations that participate in the GIVD statistics, from Austria, Belgium, the Czech Republic, Denmark, France, Germany, Italy, the Netherlands, Poland, Portugal, Slovakia, Spain and the United Kingdom. The Parties estimate that 77 companies participate in these statistics, representing approximately 80% of total IVD sales in the EEA.

⁵³ Analysers are commonly placed at the customer's disposal for free in exchange of a minimum volume commitment in the purchase of reagents. The GIVD data concerning the revenues based on sales of analysers are underestimated/distorted.

⁵⁴ For instance, Radiometer (Danaher), who is a significant player for POC analysers in several EEA Contracting Parties, does not report to EDMA.

⁵⁵ Our market investigation indicates the overall lower reliability of GIVD data for the POC categories, which are globally less sophisticated and less detailed than for laboratory reagents. Due to the overall smaller size of the POC market, sales data for POC reagents are very sensitive to the market participant's interpretation of the relevant POC codes and willingness to provide a proper split between laboratory and POC for a same reagent.

⁵⁶ Based on the functional analysis provided in Annex 7.26 of the Form CO. E.g. in the area of blood gas testing, Abbott's i-STAT has a maximal throughput rate of 20 tests per hour while certain analysers of Roche's Cobas b series can perform up to 360 tests per hour.

Market shares based on current installed base of analysers

- (72) Both for the laboratory and POC IVD market, the installed base of analysers has been estimated to illustrate the Parties' and their competitors' positions. The installed base reflects the number of analysers sold in the past and that are considered to be still currently in use.
- (73) Concerning the laboratory segment, current installed base has been estimated based on a business intelligence report commissioned by Abbott in 2015 to *[third party consultant]*. The data available in this report provides a split into clinical chemistry analysers and immunochemistry analysers for Europe overall. Further estimations at national EEA level has been done by the Parties.
- (74) Concerning the POC segment, the installed base has been estimated by the Parties in each EEA Contracting Parties for which Alere has a direct sales presence. Competitor's analysers have been regrouped into a "blood gas and haematology" group and "cardiac markers and coagulation" group, because of the overall proximity in the testing menu of these different analysers. Abbott's i-STAT is the only POC analyser to appear in both groups.

4.3.2. *POC*

4.3.2.1. **Blood gas**

(a) The Parties' products

- (75) In blood gas testing, Abbott supplies the analyser i-STAT and Alere EPOC, together with all the reagents. The Parties' products are fully portable solutions ("handheld" analysers), that is, they have the size of a small scanning device, run on a battery and can be put in the pocket of the robe of medical personnel for testing at patients' bedside.
- (76) The i-STAT, Abbott's handheld device, weighs 635 grams and offers a wide testing menu ranging from clinical chemistry and haematology to immunochemistry and coagulation tests. Its turnaround time is between 2 and 10 minutes.
- (77) A version of the i-STAT, called VetScan i-STAT is commercialised by Abaxis Inc ("Abaxis", USA) for veterinary purposes, under a worldwide exclusive arrangement with Abbott. Abbott owns all necessary IP rights and manufactures VetScan i-STAT. The Abaxis brand name is also on the device's cover, which [Confidential details on Abbott's relationship with Abaxis].
- (78) The EPOC is a handheld device weighing 680 grams used for testing blood gas, electrolytes and metabolites at the patient's bedside in approximately 30 seconds.
- (79) The EPOC is also used for veterinary purposes. Analysers and reagents are manufactured by Alere (under the trade name Epocal) and commercialised under a world-wide distribution agreement by Woodley Equipment Company Ltd ("Woodley", United Kingdom).
- (80) For both systems used for veterinary purposes, the analysers and the reagents for veterinary use are basically the same as those for human use, although the test parameters may differ depending on the animal species being tested. In order to

prevent interchangeability and misuse, barcodes are bespoke (i.e. an analyser for human use cannot read a veterinary cartridge and vice versa).

(b) Competitive assessment

(i) Human health

The Notifying Party's view

- (81) The Notifying Party considers that the Transaction does not give rise to competition concerns in any hypothetical segment for POC analysers testing for blood gas.
- (82) According to past decisional practice,⁵⁷ concerns are more likely on markets where the Parties' combined market shares exceed 35% and the increment of the Transaction exceeds 1% (Group 1 markets); the Commission thus focused its analysis on those markets. The Parties' combined installed base gives rise to Group 1 markets in Luxembourg (combined market share of [70-80]%, increment of [10-20]%), France (combined market share of [30-40]%, increment of [10-20]%) and Sweden (combined market share of [30-40]%, increment of [0-5]%).⁵⁸ The Notifying Party considers that they face strong competition from large, established and well-resourced international suppliers such as Danaher/Radiometer, Siemens, Roche and Werfen/IL that compete across the European Union and globally.
- (83) The Notifying Party also considers that the Parties are not close competitors according to tender data analysis and sales data analysis and that reagent sales data clearly shows the Parties' moderate position in the market.

The Commission's assessment

- (84) To assess the Parties' positions on the market for POC blood gas testing in human health, market shares have been estimated by the Parties both in terms of reagent sales and in terms of the installed base of analysers. Both sets of data are used as a proxy to evaluate the Parties' market position because their POC systems are closed systems.
- (85) Table 1 presents the market shares of Abbott and Alere in the narrowest plausible affected markets identified by the Notifying Party based on their reagents sale in POC blood gas testing (following the GIVD classification)⁵⁹ for 2013, 2014 and 2015.⁶⁰

⁵⁷ See in particular M.5661, *Abbott/ Solvay Pharmaceuticals*, 11/02/2010, para 50; M.6175, *Danaher/Beckman Coulter*, 16/06/2011, para 37; M.6293, *Thermo Fisher/ Phadia*, 18/08/2011, para 26.

⁵⁸ The Transaction did not give rise to any Group 1+ markets (markets falling into one of the following scenarios: (1) the combined market share is below 35% BUT only one other competitor remains on the market; and (2) the combined market share exceeds 35% and the increment is below 1% but the party with the small increment is a recent entrant).

⁵⁹ For blood gas testing, the Parties used GIVD codes for of all electrode cartridges (GIVD level 3) or for multi-panel electrode cartridges for blood gas testing (GIVD level 4).

⁶⁰ For reagent sales data, estimates of the overall national market sizes do not fluctuate significantly over the period and Table 1 indicates the overall market sizes for 2015. Table 1 indicates market share ranges, compatible with the available data over the last 3 years and gathers market information on each national market which was affected in either 2013, 2014 or 2015. Non-affected markets listed in the table (which are affected at least for one plausible market segment) are displayed in italic.

Table 1 – Market shares of the Parties in POC reagents for blood gas testing, 2013-2015

POC Reagents for blood gas testing								
All electrode cartridges for blood gas testing (level 3 - 11.70.31)					Multi-panel electrode cartridges for blood gas, metabolites and specific ion testing (level 4 - 11.70.31.05)			
Country	Market size (M€)	Abbott Share	Alere Share	Combined Share	Market size (M€)	Abbott Share	Alere Share	Combined Share
Finland	[EUR 1-5 million]	20-30%	0-5%	20-30%	[EUR 1-5 million]	25-35%	0-5%	25-35%
Netherlands	[EUR 1-5 million]	20-30%	0-5%	20-30%	[EUR 1-5 million]	30-40%	0-5%	30-40%
Luxembourg	[EUR 1-5 million]	20-30%	0-5%	20-30%	[below EUR 1 million]	30-40%	0-5%	30-40%
Norway	[below EUR 1 million]	10-20%	10-20%	20-30%	[below EUR 1 million]	10-20%	10-20%	20-30%
Romania	[EUR 1-5 million]	0-5%	10-20%	10-20%	[EUR 1-5 million]	0-5%	20-30%	20-30%

Source: Parties' best estimates, based on Annex 7.01 of the Form CO.

- (86) Table 2 presents the market shares of Abbott, Alere and their competitors in the narrowest plausible affected markets identified by the Parties based on their current installed base of analysers. A distinction is made between an overall market comprising all POC devices and a narrower market of handheld POC devices only.

Table 2 – Market shares of the Parties and their main competitors in POC blood gas analysers, 2015⁶¹

Installed base of POC blood gas analysers												
Country	overall POC (benchtop and handheld)								handheld POC			
	Market size (units)	Abbott Share	Alere Share	Combined Share	Shares of main competitors				Market size (units)	Abbott Share	Alere Share	Combined Share
					Danaher	Siemens	Roche	IL				
Luxembourg	[below 500]	60-70%	10-20%	70-80%	5-10%		10-20%	5-10%	[below 500]	80-90%	10-20%	100%
France	[between 1000-2000]	10-20%	20-30%	30-40%	20-30%	0-5%	5-10%	10-20%	[below 500]	40-50%	50-60%	100%
Sweden	[between 500-1000]	30-40%	0-5%	30-40%	40-50%	5-10%		5-10%	[below 500]	90-100%	5-10%	100%
Germany	[between 7000-8000]	5-10%	10-20%	20-30%	20-30%	5-10%	20-30%	10-20%	[between 1000-2000]	30-40%	60-70%	100%
Norway	[below 500]	10-20%	5-10%	20-30%	60-70%	5-10%	0-5%	0-5%	[below 500]	50-60%	40-50%	100%
United Kingdom	[between 2000-3000]	10-20%	5-10%	20-30%	10-20%	10-20%	20-30%	10-20%	[between 500-1000]	70-80%	20-30%	100%
Ireland	[below 500]	20-30%	0-5%	20-30%	10-20%	10-20%	20-30%	10-20%	[below 500]	90-100%	5-10%	100%
Netherlands	[between 500-1000]	10-20%	0-5%	20-30%	20-30%	10-20%	10-20%	10-20%	[below 500]	80-90%	10-20%	100%
Austria	[between 500-1000]	5-10%	5-10%	10-20%	30-40%	5-10%	30-40%	5-10%	[below 500]	50-60%	40-50%	100%
Belgium	[below 500]	5-10%	5-10%	10-20%	20-30%	30-40%	10-20%	10-20%	[below 500]	40-50%	50-60%	100%
Portugal	[between 500-1000]	10-20%	0-5%	10-20%	40-50%	0-5%	0-5%	30-40%	[below 500]	80-90%	10-20%	100%
Italy	[between 4000-5000]	5-10%	0-5%	10-20%	20-30%	10-20%	0-5%	30-40%	[below 500]	70-80%	20-30%	100%
Finland	[below 500]	0-5%	5-10%	5-10%	40-50%	30-40%		10-20%	[below 500]	5-10%	90-100%	100%
Denmark	[below 500]	5-10%	0-5%	5-10%	90-100%				[below 500]	80-90%	10-20%	100%
Spain	[between 4000-5000]	0-5%	0-5%	0-5%	30-40%	5-10%	10-20%	40-50%	[below 500]	30-40%	60-70%	100%

Source: Parties' best estimates, based on Annex 7.27 of the Form CO. Market information was provided only for countries where Alere has a direct presence although the Parties' activities also overlap in Iceland, Romania, Greece and Poland (Form CO, Annex 7.01).

- (87) The above tables show that, based on IVD reagent sales or installed base of overall POC devices, the combined market shares of the Parties in the market for the supply of blood gas POC analysers is generally in the range of [20-30]% based on reagents sale (irrespective of whether single-test cartridges are included or not in the relevant product market). However, as explained above, reagents sale in the POC sector need to be considered with certain precaution and may not be the right proxy to evaluate the Parties' position for the POC blood gas overall systems. Based on their current installed base of analysers, the Parties combined market share reaches up to [30-40]% in France and Sweden and [70-80%] in Luxembourg. More importantly, if the market was to be limited to the most portable handheld devices, the Parties are the only competitors present, and the Transaction will then lead to a monopoly situation in the 19 EEA Contracting Parties in which both Parties are active.
- (88) As to the competitors, four main players are also active in the POC blood gas markets in the EEA, Radiometer (Danaher), Siemens, Roche and IL (Werfen). All of

⁶¹ Non-affected markets listed in the table (which are affected at least for one plausible market segment) below are displayed in italic.

them only offer benchtop devices which are heavier (weighting between 2.4kg up to over 30kg) and therefore much more difficult to move around.

- (89) Smaller players, such as Lifehealth or OPTI Medical also offer intermediate "portable benchtop" devices, through their respective IRMA Trupoint and CCA devices. Based on the Parties' information, their presence is however limited [Confidential].
- (90) The results of the market investigation indicated that Abbott i-STAT is a significant player in the blood gas POC space, regularly identified among the Top 3 by customers,⁶² with EPOC being its closest competitor. Indeed, many respondents to the market investigation identified i-STAT and EPOC as being each other's closest competitor,⁶³ in particular in view of their common handled or "true bedside" feature. Some customers also mentioned that the merger will lead to a dominant or monopolistic situation on the market for handheld devices.⁶⁴
- (91) The closeness of competition is also confirmed in the Parties' internal documents. [Confidential excerpt from Parties' internal document]⁶⁵ [Confidential excerpt from Parties' internal document].⁶⁶ [Confidential excerpt from Parties' internal document].⁶⁷
- (92) In addition, some customers identified a risk of negative impact of the merger in the POC blood gas market, in particular a risk of price increase and reduced choice post-Transaction.⁶⁸ By way of example, one customer indicated that "*When it comes to hand-held instrument they will dominate the market for blood gases [...] witch may lead to higher prices and it might get harder to make demands on the products*".⁶⁹ This conclusion is also shared by competitors.⁷⁰
- (93) In view of the above, the Commission raises serious doubts as to the compatibility of the Transaction with the internal market, as it could eliminate important competitive constraints on the merged entity, consequently increasing its market power in relation to the (i) overall POC blood gas systems for human use market in the EEA in general and in Luxembourg, France, Sweden and Finland in particular and (ii) the handheld market segment in the EEA in general and in Luxembourg, France,

⁶² Responses to Questionnaire Q2 to Customers of 29 November 2016, question 29

⁶³ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 30 and responses to Questionnaire Q1 to Competitors of 29 November 2016, question 28

⁶⁴ Agreed minutes of a conference call held with a Key Opinion Leader in the field of blood gas dated 26 October 2016, para 15; See also response of a customer to Questionnaire Q2 to Customers of 29 November 2016, question 31.1: "*The merger will make ABBOTT stronger in the field of POC and will expand the portfolio. Abbott will be a dominant player in future reorganization of laboratory activity spanning from CORELAB to a single test POC analyser*".

⁶⁵ "*Cardiometabolic business unit, 5 year strategic business plan, 2015-2020*", Alere, p. 1317 (Annex 22.2.38).

⁶⁶ "*EPOC Market Insight*", Alere, 12 July 2015, p.1756 (Annex 22.2.47); See also "*Cardiometabolic business unit, 5 year strategic business plan, 2015-2020*", Alere, 2015, p. 1306 (Annex 22.2.38): "[Confidential excerpt from Parties' internal document]".

⁶⁷ "*Competitive overview, blood gas & TCM*", Abbott, 6 April 2016, p. 4, 59 and 93 (Annex 6.11.1.1).

⁶⁸ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 31.1; See also agreed minutes of a conference call held with a Key Opinion Leader in the field of blood gas dated 26 October 2016, para 15

⁶⁹ Response of a customer to Questionnaire Q2 to Customers of 29 November 2016, question 31.1

⁷⁰ Responses to Questionnaire Q1 to Competitors of 29 November 2016, question 29

Sweden, Germany, Norway, United Kingdom, Ireland, the Netherlands, Austria, Belgium, Portugal, Italy, Finland, Denmark, Spain, Iceland, Romania, Greece and Poland in particular.

(ii) Animal health

The Notifying Party's view

- (94) The Notifying Party considers that there is no overlap between Abbott and Alere in the veterinary segment of the IVD sector in the EEA, because only Alere is active in this area in the EEA, and only at the wholesale level. Indeed, [Confidential details on Alere's sales in the veterinary segment] of Alere sales of the EPOC for veterinary use in the EEA are made directly to Woodley Equipment.
- (95) The Notifying Party considers that Abbott's activities are limited to the toll manufacturing of i-STAT instruments and corresponding cartridges for veterinary use on behalf of Abaxis, which exclusively supplies the VetScan i-STAT globally. Therefore, the Notifying Party considers that the only overlap is at the manufacturing level, where the Parties would have a *de minimis* presence in a hypothetical market for contract manufacturing of all IVD products globally.
- (96) The Notifying Party also considers that there are a large number of competitive products in the blood gas segment of the veterinary IVD sector such as the Radiometer ABL, the Roche Cobas, the Life Health IRMA TruPoint and the Idexx Laboratories VetStat.

The Commission's assessment

- (97) Contrary to the Notifying Party's view, the Commission considers that in the veterinary space, Abbott does not act as a mere contract manufacturer for Abaxis. Abbott holds all the know-how and IP rights for the manufacturing and supply of i-STAT and Abaxis acts essentially as an exclusive distributor. In case of termination of the Abaxis agreement, Abbott could sell its product directly or find alternative distributors/partners. As a consequence, the Commission assesses below the horizontal overlap between Abbott and Alere's activities in the supply of animal POC blood gas testing systems.
- (98) In the veterinary area, for the overall market of veterinary POC blood gas testing, the Parties provided their best estimates of market shares in 16 EEA Contracting Parties and identified affected markets in all these countries.⁷¹
- (99) More specifically, the Parties submitted that Abbott i-STAT (through its distributor Abaxis) is generally n°2 with [20-30]% of market share, followed by Alere EPOC n°3 with [5-10]% which is the last entrant, while Idexx Laboratories VetStat would lead the market with a [40-50]% market share. If a market limited to handheld device is considered, the combined market shares of the Parties would reach 100% in all overlapping 16 EEA Contracting Parties. Idexx Laboratories in particular offers a middle-sized benchtop device dedicated to veterinary use.

⁷¹ Austria, Norway, Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Poland, Portugal, Spain, Sweden and the United Kingdom.

- (100) The results of the market investigation indicated that the veterinary IVD market for POC blood gas testing in the EEA is rather concentrated. Similarly to the human health segment, the Parties are the only competitors to provide a truly portable solution, which the market investigation confirmed to be a key feature for veterinaries as explained above. Abbott's VetScan i-STAT and Alere's EPOC are the sole alternatives for end customers for handheld devices.
- (101) The proximity between the two devices was confirmed during the market investigation⁷². Abbott's VetScan i-STAT and Alere's EPOC "*are the smallest and only portable devices on the market of animal blood gas testing. Both have the size of a small hand luggage, operate with batteries, are single-cartridge devices and have similar testing menus*"⁷³.
- (102) Some customers identified a risk of price increase or reduced choice post-Transaction in the market for POC animal blood gas testing⁷⁴, especially as the market is rather concentrated and small.⁷⁵
- (103) In view of the above, the Commission raises serious doubts as to the compatibility of the Transaction with the internal market, as it could eliminate important competitive constraints on the merged entity, consequently increasing its market power in relation to handheld POC blood gas systems for veterinary use overall and in the handheld segment in the EEA in general and in Austria, Norway, Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Poland, Portugal, Spain, Sweden and the United Kingdom in particular.

4.3.2.2. Cardiac markers

(a) The Parties' products

- (104) In cardiac markers testing, Abbott supplies i-STAT and Alere Triage, together with all the reagents. Cardiac markers tests are only carried out in human medicine.
- (105) The i-STAT, Abbott's handheld device (635g) offers a wide testing menu ranging from clinical chemistry and haematology to immunochemistry and coagulation tests. Its turnaround time is between 2 and 10 minutes.
- (106) The Triage, Alere's device is a light benchtop device (700g) mainly testing for coronary heart disease and heart failure. Its turnaround time is between 15 and 20 minutes for the first sample and less than 2 minutes for the other tests on the same sample.

(b) Competitive assessment

The Notifying Party's view

- (107) The Notifying Party considers that the Transaction would not give rise to competition concerns although the existence of a certain number of Group 1 shares

⁷² Responses to Questionnaire R3 to Customers in the veterinary space of 5 January 2017, question 2

⁷³ Agreed minutes of a conference call held with a customer dated 21 December 2016, para 12

⁷⁴ Responses to Questionnaire R3 to Customers in the veterinary space of 5 January 2017, question 3.1

⁷⁵ Agreed minutes of a conference call held with a Key Opinion Leader in the field of blood gas in the veterinary space dated 21 December 2016, para 15

based on the installed base of cardiac markers analysers, in Belgium (combined market share of [50-60]%, increment of [5-10]%), Germany (combined market share of [40-50]%, increment of [5-10]%), Ireland (combined market share of [70-80]%, increment of [20-50]%), Italy (combined market share of [50-60]%, increment of [10-20]%), Luxembourg (combined market share of [50-60]%, increment of [10-20]%) and Sweden (combined market share of [50-60]%, increment of [5-10]%).

- (108) The Notifying party considers that the installed base data do not reflect the usage patterns of multi-test panel platforms offering both cardiac and coagulation testing, but also other tests such as drugs of abuse testing, infectious diseases and various immunochemistry tests. The Notifying Party underlines that the installed base estimates are overstating the Parties' market position according to reagent sales data.
- (109) The Notifying Party considers that there is an intense competition in the POC cardiac testing segment from strong competitors such as Danaher/Radiometer, Siemens, Roche, Samsung, and Mitsubishi, but also from core laboratory testing competitors, whose constraints on the use of POC devices for cardiac marker testing should not be ignored in the competitive analysis.
- (110) [Confidential information on Abbott's current strategy in cardiac markers business].
- (111) The Notifying Party finally considers that the Parties are not close competitors according to tender data analysis and sales data analysis and that the revenues of the Parties for POC devices in the EEA are limited.

The Commission's assessment

- (112) To assess the Parties' positions on the market for POC cardiac markers testing, market shares have been estimated by the Parties both in terms of reagent sales and current number of placed analysers. Both data are used as a proxy to evaluate the Parties' market position because their POC systems are closed systems.
- (113) Table 3 presents the market shares of Abbott and Alere in the narrowest plausible affected markets identified by the Notifying Party based on their reagents sales in POC cardiac market testing (following the GIVD taxonomy)⁷⁶ for 2013, 2014 and 2015.⁷⁷

⁷⁶ For cardiac marker testing, the Parties used GIVD codes for of all cardiac markers (GIVD level 3) or the narrower markets of Troponin testing or BNP/pro-BNP testing (GIVD level 4).

⁷⁷ For reagent sales data, estimates of the overall national market sizes do not fluctuate significantly over the period and Table 3 indicates the overall market sizes for 2015. Table 3 here below indicates market share ranges, compatible with the available data over the last 3 years and gathers market information on each national market which was affected in either 2013, 2014 or 2015. Non-affected markets listed in the table (which are affected at least for one plausible market segment) are displayed in italic.

Table 3 – Market shares of the Parties in POC reagents for cardiac markers testing, 2013-2015

Country	POC Reagents for cardiac markers testing											
	All cardiac marker testing (level 3 - 12.70.13)				Troponin (level 4 - 12.70.13.03)				BNP / pro-BNP (level 4 - 12.70.13.04)			
	Market size (M€)	Abbott Share	Alere Share	Combined Share	Market size (M€)	Abbott Share	Alere Share	Combined Share	Market size (M€)	Abbott Share	Alere Share	Combined Share
Romania	[EUR 1-5 million]	0-5%	30-40%	30-40%	[below EUR 1 million]	0-5%	0-5%	5-10%				
Germany	[EUR 20-30 million]	0-5%	25-35%	25-35%	[EUR 1-5 million]	5-10%	10-20%	20-30%	[EUR 5-10 million]	0-5%	10-20%	10-20%
Belgium	[EUR 1-5 million]	0-5%	20-30%	20-30%	[below EUR 1 million]	5-15%	10-20%	20-35%	[EUR 1-5 million]	0-5%	20-30%	20-30%
Ireland	[EUR 1-5 million]	0-5%	20-30%	20-30%	[EUR 1-5 million]	0-5%	0-5%	5-10%	[EUR 1-5 million]	0-5%	15-25%	20-30%
Greece	[below EUR 1 million]	5-10%	10-20%	20-30%	[below EUR 1 million]	0-10%	0-10%	5-10%	[below EUR 1 million]	0-10%	0-10%	5-15%
Finland	[EUR 1-5 million]	5-10%	5-10%	10-20%	[below EUR 1 million]	25-35%	0-5%	30-40%	[below EUR 1 million]	0-5%	10-20%	10-20%
France	[EUR 20-30 million]	0-5%	10-20%	10-20%	[below EUR 1 million]	10-20%	5-15%	20-30%	[EUR 20-30 million]	0-5%	5-15%	5-15%
Portugal	[EUR 1-5 million]	5-10%	0-5%	5-10%	[below EUR 1 million]	20-30%	0-5%	20-30%				
Sweden	[EUR 1-5 million]	0-5%	0-5%	0-5%	[below EUR 1 million]	20-30%	0-5%	20-30%	[below EUR 1 million]	0-5%	0-5%	0-5%

Source: Parties' best estimates, based on Annex 7.01 of the Form CO.

(114) Table 4 presents the market shares of Abbott, Alere and their competitors in the narrowest plausible affected markets identified by the Parties based on their current installed base of analysers of POC cardiac markers analysers.

Table 4 - Market shares of the Parties and their main competitors in POC cardiac markers, 2015

Country	Installed base of POC analysers for cardiac markers									
	overall POC (benchtop and handheld)									
	Market size (units)	Abbott Share	Alere Share	Combined Share	Shares of main competitors					
					Danaher	Mitsubishi	Roche	Samsung	Siemens	
Ireland	[below 500]	20-30%	50-60%	70-80%	0-5%		10-20%	0-5%		
France	[below 500]	10-20%	40-50%	60-70%	20-30%	5-10%	0-5%		0-5%	
Italy	[between 1000-2000]	10-20%	40-50%	50-60%	5-10%	5-10%	0-5%	0-5%	20-30%	
Sweden	[below 500]	40-50%	5-10%	50-60%	5-10%		20-30%		5-10%	
Luxembourg	[below 500]	10-20%	30-40%	50-60%	10-20%		30-40%		5-10%	
Belgium	[below 500]	5-10%	50-60%	50-60%	5-10%	0-5%	30-40%	0-5%	0-5%	
Germany	[between 4000-5000]	5-10%	30-40%	30-40%	5-10%	0-5%	40-50%		5-10%	
United Kingdom	[between 500-1000]	10-20%	10-20%	30-40%	0-5%	0-5%	50-60%	0-5%	0-5%	
Netherlands	[below 500]	10-20%	10-20%	20-30%	10-20%	0-5%	50-60%	0-5%	0-5%	

Source: Parties' best estimates, based on Annex 7.32 of the Form CO. Market information was provided only for countries [Confidential] (9 affected Member States listed in the Table and non-affected markets for Norway, Austria, Portugal, Finland, Denmark and Spain) although the Parties' activities also overlap in Romania, Poland and Greece (Annex 7.01).

- (115) Out of the 18 EEA Contracting Parties in which both Parties are active, the Parties' best estimate of installed base show that the Transaction would lead to affected markets in the nine EEA Contracting Parties listed in table 4.
- (116) The above tables show that, based on IVD reagent sales or installed base of overall POC devices, the combined market shares of the Parties in the market for the supply of cardiac marker POC analysers is generally in the range of [20-30]% based on reagents sale, with a combined market share up to [30-40]% in Romania for all cardiac markers and in Finland for Troponin tests only. However, as explained above, reagents sale in the POC sector need to be considered with certain precaution and may not be the right proxy to evaluate the Parties' position for the POC cardiac marker overall systems. Based on their current installed base of analysers, the Parties combined market share reaches up to [50-60]% in Italy, Sweden, Luxembourg and Belgium, [60-70]% in France and [70-80%] in Ireland, with an increment above [10-20]% in four of these Member States.
- (117) As to the competitors, five other players are active in the POC cardiac markers markets in the EEA, including Radiometer (Danaher), Siemens, Roche (Cobas) and Mitsubishi. Samsung is also active in the EEA but with market shares always below [5-10]%. Radiometer, Siemens and Mitsubishi offer heavier benchtop analysers (35kg for Radiometers') and turnaround time of 15-20 minutes. Triage, i-STAT and Cobas' analysers weight approximately 500-700g and provide faster results.
- (118) The results of the market investigation indicated that Alere Triage is a significant player in the cardiac markers POC space, identified as number 1 by some customers at national level and within the top 3 by competitors at EEA level.⁷⁸
- (119) Many respondents to the market investigation identified i-STAT and Triage as being close competitors.⁷⁹ In particular, some respondents identified Siemens, Radiometer and Mitsubishi with their benchtop device as more distant competitors to Triage, with i-STAT and Triage's having the advantage of being portable.⁸⁰ In its internal documents, Alere also mentions as an argument to customers to switch to Alere that [Confidential excerpt from Parties' internal document].⁸¹
- (120) The impact of the Transaction in the market for cardiac markers POC systems, through the combination of the Parties' small-sized analysers have been identified by market participants. One competitor indicated that "*after the merger Abbott/Alere would take about 1/3 of EU POC cardiac market in general. If the focus is only on small systems (excluding benchtops like the Siemens Stratus, Radiometer AQT90, Mitsubishi Pathfast, etc.) that could be used in a near-patient setting the combined market share of Abbott/Alere is anticipated to be >50%*",⁸² while another indicated that "*in the bedside cardiac markers for POC segment, Abbott iStat, Alere Triage [...] are close and leading competitors with very few alternatives*".⁸³ This is also

⁷⁸ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 29 and responses to Questionnaire Q1 to Competitors of 29 November 2016, question 26

⁷⁹ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 30 and responses to Questionnaire Q1 to Competitors of 29 November 2016, question 28

⁸⁰ Response of a customer to Questionnaire Q2 of 29 November 2016 to question 28.2 and the response of a competitor to Questionnaire Q1 of 29 November 2016, question 25.2

⁸¹ "Alere Triage System Product Profile", Alere, October 2015, p. 2296 (Annex 22.2.64)

⁸² Response of a competitor to Questionnaire Q1 of 29 November 2016, question 26.1

⁸³ Response of a competitor to Questionnaire Q1 of 29 November 2016, question 29.1

confirmed by customers, with one of them indicating that "*for cardiac markers they [the Parties] will become rather dominant*".⁸⁴

- (121) In view of the above, and in particular the combined position and closeness of competition between the products of Abbott (i-STAT) and Alere (Triage), the Commission raises serious doubts as to the compatibility of the Transaction with the internal market, as it could eliminate important competitive constraints on the merged entity, consequently increasing its market power in relation to the POC cardiac markers market in the EEA in general and in Ireland, France, Italy, Sweden, Belgium, Luxembourg, Belgium, Germany, United Kingdom and the Netherlands in particular.

4.3.3. *Laboratory*

4.3.3.1. **Horizontal overlaps**

- (122) In the laboratory segment, the overlaps between the activities of the Parties are limited since Alere does not offer own-branded laboratory analysers. Alere [Confidential details on Alere's activities in the laboratory segment] re-sells third party manufactured analysers and [Confidential details on Alere's activities in the laboratory segment] re-sells third party manufactured and labelled reagents for laboratory analysers in the EEA.⁸⁵
- (123) The Parties identified the markets affected by the Transaction both with regards to sales of analysers and of reagents. Indeed, Alere is not active for the supply of full IVD laboratory systems.

(a) Analysers

- (124) The Parties estimated their market shares under any plausible market definition, including in particular Alere's activities as a re-seller, based on the current installed base of analysers.
- (125) The proposed Transaction would give rise to only one affected market in the narrower segment for clinical chemistry laboratory analysers in Norway, with Abbott having [10-20]% and Alere [10-20]% of market share.
- (126) However, the Parties' combined position is limited and the Parties' products are not directly competing since Alere only resells Tosoh's HLC analyser which is designed to run only one clinical chemistry test (HbA1c analyte), as opposed to Abbott's product offering for clinical chemistry, the Architect c series, which covers around 100 different analytes in this specific IVD area.

⁸⁴ Response of a customer to Questionnaire Q2 of 29 November 2016, question 31.1

⁸⁵ In the markets where Alere is re-selling, the latter does not exert the same competitive constraint on Abbott as if it were selling its own branded products. Indeed, if Alere stops its activities following the merger, this would likely not result in the elimination of the products it currently resells from the market. Instead, the manufacturer could vertically integrate and start distributing its own products or find an alternative distributor that could maintain the same market position, if it is as efficient as Alere. Moreover, in many instances Alere is only one of several distributors, which could quickly expand their sales if post-Transaction Alere ceases or reduces its distribution activities. Therefore, the fact that the competitive pressure Alere exerts on Abbott pre-Transaction is reduced will be taken into account, as one of several elements, in the Commission's analysis of the impact of the Transaction on these markets.

(127) In view of the above, the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the supply of analysers.

(b) Reagents

(128) The Parties estimated their market shares under any plausible market definition, including in particular Alere's activities as a re-seller, based on reagent sales using the available GIVD data. Under this approach, which investigates the market under its narrowest possible segmentation, the proposed Transaction would lead to an important number of technically affected markets, most of which are however unlikely to raise serious doubts as to its compatibility with the internal market due to Alere's limited presence.

(129) More specifically, the Notifying Party identified within all possible affected markets the Group 1 markets, on which it focused its analysis. Within the broad IVD categories, Group 1 markets arose in the supply of reagents for clinical and immunochemistry, as well as for infectious diseases.

(i) *Clinical chemistry and immunochemistry*

(130) Table 5 below presents all affected markets related to any level 3 or level 4 category of GIVD, namely, to the narrowest plausible product markets, in the field of clinical chemistry and immunochemistry, for which at least one national market is a Group 1 market based on either 2013, 2014 or 2015 data.⁸⁶ It is however worth noting that only for bile acids in the United Kingdom a Group 1 market arose in 2015.

⁸⁶ The list comprises Group 1 markets arising in areas where the Parties' activities compete, and are not complementary. A level 1, 2, 3 or 4 GIVD category has not been included in the table, if it groups a variety of activities and the Parties' only undertake objectively different activities within that GIVD category (irrespective of the –artificially- reported combined market share within that category).

Table 5 – Market shares of the Parties in LAB reagents for clinical chemistry and immunochemistry, in relevant affected markets, 2013-2015⁸⁷

LAB reagents for clinical chemistry and immunochemistry					
relevant GIVD level 3 or 4					
Category	Country	Market size (M€)	Abbott Share	Alere Share	Combined Share
Alanine Amino-Transferase	Sweden	[below EUR 1 million]	20-30%	0-15%	20-40%
	Finland	[below EUR 1 million]	10-20%	0-5%	20-30%
	United Kingdom	[EUR 1-5 million]	25-35%	0-5%	25-35%
Bile acids	United Kingdom	[below EUR 1 million]	15-35%	30-40%	55-70%
	Poland	[below EUR 1 million]	0-10%	15-25%	20-35%
	Sweden	[below EUR 1 million]	20-30%	0-5%	20-30%
Creatinine	Sweden	[below EUR 1 million]	30-40%	0-5%	30-40%
	United Kingdom	[EUR 1-5 million]	20-30%	0-5%	20-30%
	Finland	[below EUR 1 million]	30-40%	0-5%	30-40%
Free prostatic specific antigen	Austria	[below EUR 1 million]	30-40%	0-5%	30-40%
Fecal Occult Blood	Italy	[below EUR 1 million]	10-25%	5-30%	20-45%
Vitamin B12	Germany	[EUR 5-10 million]	35-45%	0-5%	35-45%
	Finland	[EUR 1-5 million]	30-40%	0-5%	30-40%
	France	[EUR 1-5 million]	10-20%	0-5%	20-30%
	Poland	[below EUR 1 million]	20-30%	0-5%	20-30%
	Slovakia	[below EUR 1 million]	20-30%	0-5%	20-30%
Methotrexate	United Kingdom	[below EUR 1 million]	40-50%	0-5%	40-50%
Cyclosporine	United Kingdom	[below EUR 1 million]	55-65%	0-5%	60-70%
Homocysteine	Belgium	[below EUR 1 million]	20-35%	5-15%	30-45%
	Bulgaria	[below EUR 1 million]	20-30%	0-5%	20-30%
	Czech Republic	[below EUR 1 million]	10-20%	5-10%	20-30%
	France	[below EUR 1 million]	20-30%	0-5%	20-30%
	Italy	[EUR 5-10 million]	25-35%	0-10%	30-45%
	Latvia	[below EUR 1 million]	20-30%	0-5%	20-30%
	Netherlands	[below EUR 1 million]	15-25%	5-10%	25-35%
	Norway	[below EUR 1 million]	10-20%	5-10%	20-30%
	Poland	[below EUR 1 million]	20-30%	0-5%	20-30%
	Spain	[EUR 1-5 million]	20-30%	0-5%	20-30%
	Sweden	[below EUR 1 million]	10-20%	5-10%	20-30%
	United Kingdom	[below EUR 1 million]	10-20%	5-10%	20-30%

Source:

Parties' best estimates, based on Annex 7.01 of the Form CO.

⁸⁷ Given the overall stability of the different national market sizes over the 3 last years, market size data provided here below corresponds to the most recent year in which each national market was affected. Parties' individual and combined market shares are, similarly as in Tables 1-4, indicated in ranges compatible with the available data for the 3 last years.

- (131) The Commission investigated the possible impact of the Transaction in all the above-mentioned markets.
- (132) Among those markets, only one gave rise to a Group 1 in 2015, namely the market for bile acids in the United Kingdom. For all other markets for laboratory reagents for clinical chemistry and immunochemistry, the situation is as follows:
- (a) Group 1 markets in 2013 and/or 2014: Alanine amino-transferase and creatinine in Sweden, Free prostatic specific antigen in Austria, Fecal occult blood in Italy, Vitamin B12 in Germany, Methotrexate in the United Kingdom, Cyclosporine in the United Kingdom, Homocysteine in Belgium and Italy;
 - (b) Affected markets (non-Group 1) in 2013, 2014 and/or 2015 for products giving rise to Group 1 markets in at least one other EEA Contracting Party: Alanine amino-transferase in Finland and the United Kingdom, bile acids in Poland and Sweden, Creatinine in Finland and the United Kingdom, Vitamin B12 in Finland, France, Poland and Slovakia, and Homocysteine in Bulgaria, Czech Republic, France, Latvia, the Netherlands, Norway, Poland, Spain, Sweden and the United Kingdom.
- (133) On many of the above-mentioned plausible markets, Alere is only re-selling third party branded products⁸⁸ and its share has been decreasing over the last three years.⁸⁹ In addition, on all those markets a number of other credible competitors are active and expected to continue constraining the merged entity. Last, the results of the market investigation did not identify any competition concerns.
- (134) The following sections of the Decision focus on products giving rise to a Group 1 market in 2015 (bile acids in the United Kingdom) or to a combined market share above 50% in 2013, 2014 or 2015 (cyclosporine in the United Kingdom).

1. Bile acids in the United Kingdom

- (135) The Parties had a combined market share between 50% and 70% for the last three years in the United Kingdom for the supply of bile acids reagents, with each Party having a similar market share. However, Alere is only re-selling bile acids manufactured and labelled under the Diazyme brand and is not its exclusive distributor.
- (136) Post-Transaction, Diazyme will have alternative distribution routes if Alere stops its re-selling activities to favour the merged entity's own offering. First, Alphalabs is currently also re-selling Diazyme bile acids in the United Kingdom. In addition,

⁸⁸ Alere is selling own-branded products on markets for homocysteine and vitamin 12 in the EEA; however, no serious doubts arise as to the compatibility of the Transaction with the internal market on any of those markets. For homocysteine, the combined market share of the Parties was below [30-40]% in the last two years in Bulgaria, Czech Republic, France, Latvia, Norway, Poland, Spain, the Netherlands and the United Kingdom. In Belgium and Italy, where the combined market share was above [30-40]%, Alere's market share has been decreasing over the last three years (from [10-20]% in 2013 to [5-10]% in 2015 in Belgium and from [5-10]% to [0-5]% in Italy). For vitamin B12, the market share of Alere was below [0-5]% in all countries over the last three years.

⁸⁹ This was not the case on markets for bile acids in Poland and Sweden, where, although not decreasing, the combined market share of the Parties has not exceeded [30-40]% over the last three years.

other distributors such as Una Health and Elitech are active in the markets, and do not currently re-sell bile acids but could do so.

- (137) The market investigation also indicated the existence of competitors, in addition to Abbott and Diazyme, including in particular Danaher (Beckman Coulter).⁹⁰ Respondents to the market investigation indicated that there is a degree of demand-side substitutability regarding bile acids reagents, as most systems are open and a number of different reagents are available on the market. A customer further pointed out that other testing techniques may be used for the same diagnostic purposes.⁹¹
- (138) Finally, no respondent to the market investigation identified a negative impact of the Transaction in the market for bile acids reagents in the United Kingdom.
- (139) In view of the above, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to bile acids in the United Kingdom.

2. Cyclosporine in the United Kingdom

- (140) The Transaction gives rise to a Group 1 market for cyclosporine in the United Kingdom only in 2013, with a combined market share of [60-70]% and a limited increment from Alere of approximately [0-5]%.
- (141) Alere's activities declined over time, with sales in 2013 and 2014 of [Confidential] in total and [Confidential] in 2015 in the United Kingdom or in any other Member States. In addition, Alere's turnover in 2013 and 2014 related to re-selling activities of Abbott's reagents.
- (142) Post-Transaction, competitors such as Danaher (Beckman Coulter), Werfen (IL) and Ortho Clinical will remain.
- (143) In view of the above, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to cyclosporine in the United Kingdom.

Conclusion

- (144) In view of the above, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to laboratory IVD systems for clinical chemistry and immunochemistry testing.

(ii) Infectious diseases

- (145) Table 6 here below presents all affected markets related to any level 3 or level 4 category of GIVD, namely, to the narrowest plausible product markets, of infectious diseases, for which at least one other national market was a Group 1 market in either 2013, 2014 or 2015.⁹²

⁹⁰ Response of a customer to Questionnaire Q2 to Customers of 29 November 2016, question 48

⁹¹ Responses of customers to Questionnaire Q2 of 29 November 2016, question 47

⁹² The list comprises Group 1 markets arising in areas where the Parties' activities compete, and are not complementary. If a level 1, 2, 3 or 4 level of GIVD was technically a Group 1 because the category grouped varied activities and the Parties' activities were indeed different, it is not included in the table.

Table 6 - Market shares of the Parties in LAB reagents for infectious diseases in relevant affected markets, 2013-2015

LAB reagents for infectious diseases					
relevant GIVD level 3 or 4					
Category	Country	Market size (M€)	Abbott Share	Alere Share	Combined Share
Chlamydia	Spain	[below EUR 1 million]	0-5%	30-40%	30-40%
	Austria	[below EUR 1 million]	20-30%	0-5%	20-30%
Syphilis	United Kingdom	[EUR 5-10 million]	35-45%	0-5%	40-50%
	Spain	[EUR 1-5 million]	30-40%	5-15%	40-50%
	Austria	[below EUR 1 million]	40-50%	0-5%	40-50%
	Belgium	[below EUR 1 million]	20-30%	0-5%	20-30%
	Czech Republic	[EUR 1-5 million]	30-40%	0-5%	30-40%
	Germany	[EUR 1-5 million]	20-30%	0-5%	20-30%
	Greece	[EUR 1-5 million]	55-65%	0-5%	55-65%
	Hungary	[below EUR 1 million]	70-80%	0-5%	70-80%
	Italy	[EUR 5-10 million]	50-60%	0-5%	50-60%
	Norway	[EUR 1-5 million]	20-30%	0-5%	20-30%
	Portugal	[below EUR 1 million]	25-35%	0-5%	30-40%
	Slovakia	[below EUR 1 million]	35-60%	0-5%	35-60%
	Syphilis Antibody	United Kingdom	[EUR 5-10 million]	35-45%	0-5%
Spain		[EUR 1-5 million]	30-40%	5-10%	40-50%
Portugal		[below EUR 1 million]	30-40%	0-5%	30-40%
Norway		[EUR 1-5 million]	20-30%	0-5%	20-30%
Mycobacteria	Spain	[EUR 1-5 million]	0-5%	65-75%	65-75%
Clostridium difficile	Spain	[below EUR 1 million]	0-5%	50-60%	50-60%
Hepatitis B Surface Antigen	United Kingdom	[EUR 1-5 million]	55-65%	0-5%	60-70%
Hepatitis B Surface Antibody	United Kingdom	[EUR 1-5 million]	40-50%	0-5%	50-60%
HIV multiple	Cyprus	[below EUR 1 million]	40-65%	0-5%	40-65%
	United Kingdom	[EUR 5-10 million]	50-60%	0-5%	50-60%
	Austria	[EUR 1-5 million]	50-70%	0-5%	60-70%
	Spain	[EUR 5-10 million]	40-50%	0-5%	40-50%
HIV multiple antibody	Cyprus	[below EUR 1 million]	0-5%	25-35%	25-35%
	United Kingdom	[below EUR 1 million]	20-30%	10-20%	40-50%
	Austria	[below EUR 1 million]	20-30%	0-5%	20-30%
	Spain	[EUR 1-5 million]	30-40%	0-5%	30-40%
HTLV Multiple antibody	United Kingdom	[EUR 1-5 million]	75-85%	0-5%	80-90%
Rubella virus	United Kingdom	[EUR 1-5 million]	40-50%	0-5%	40-50%
	Spain	[EUR 1-5 million]	25-35%	0-5%	30-40%
Rubella virus IgM	United Kingdom	[below EUR 1 million]	25-35%	5-20%	30-50%
	Spain	[below EUR 1 million]	20-30%	0-10%	25-35%
Cytomegalovirus	United Kingdom	[EUR 1-5 million]	40-50%	0-5%	40-50%
	Austria	[EUR 1-5 million]	50-60%	0-5%	50-60%
	Germany	[EUR 5-10 million]	25-35%	0-5%	25-35%
Cytomegalovirus IgG	United Kingdom	[EUR 1-5 million]	55-65%	0-5%	55-65%
	Austria	[below EUR 1 million]	50-60%	0-5%	50-60%
	Spain	[EUR 1-5 million]	30-40%	0-10%	30-45%
Respiratory Syncytial Virus	United Kingdom	[below EUR 1 million]	60-70%	5-10%	60-70%
Chagas	Italy	[below EUR 1 million]	25-35%	0-5%	30-40%
	Spain	[below EUR 1 million]	40-50%	0-15%	50-60%

Source: Parties' best estimates, based on Annex 7.01 of the Form CO.

- (146) The Commission investigated the possible impact of the Transaction in all the above-mentioned markets.
- (147) Among those markets, only five gave rise to Group 1 markets in 2015, namely Syphilis reagents in Spain and the United Kingdom, Syphilis antibody assays in Spain, Cytomegalovirus in the United Kingdom and Chagas in Spain. For all other markets for laboratory reagents for infectious diseases, the situation is as follows:
- (a) Group 1 markets in 2013 and/or 2014: Chlamydia in Spain, Syphilis reagents in Austria, Syphilis antibody assays in the United Kingdom, Mycobacteria in Spain, Clostridium difficile in Spain, Hepatitis B Surface antigen and antibody in the United Kingdom, HIV multiple in Cyprus and the United Kingdom, HIV multiple antibody in the United Kingdom, HTLV multiple antibody in the United Kingdom, Rubella virus and IgM in the United Kingdom, Cytomegalovirus IgG in Spain, and Respiratory Syncytial virus in the United Kingdom;
 - (b) Affected markets (but non-Group 1) in 2013, 2014 and/or 2015 for products giving rise to Group 1 markets in at least one other EEA Contracting Party: Chlamydia in Austria, Syphilis reagents in Belgium, the Czech Republic, Germany, Greece, Hungary, Italy, Norway, Portugal and Slovakia, Syphilis antibody assays in Portugal and Norway, HIV multiple in Austria and Spain, HIV multiple antibody in Cyprus, Austria and Spain, Rubella virus and IgM in Spain, Cytomegalovirus in Austria and Germany, Cytomegalovirus IgG in the United Kingdom and Austria, and Chagas in Italy.
- (148) In view of the decrease of market shares over the last three years,⁹³ the fact that Alere is primarily active through the re-selling of third-party products,⁹⁴ the fact that several credible competitors are active in these markets and will continue constraining the merged entity, as well as the results of the market investigation, which did not point towards any competition concerns, the Commission concludes that the Transaction does not lead to serious doubts as to its compatibility with the internal market in relation to infectious disease laboratory products. The Decision focuses below on the products giving rise to a Group 1 market in 2015 or to a combined market share above 50% in 2013, 2014 or 2015.

1. Chagas reagents in Spain

- (149) In 2015, the Parties' combined market share for Chagas reagents in Spain was [50-60]%, with an increment of [0-5]% from Alere. Alere only re-sold third party manufactured and labelled products from Trinity and Vircell; the latter ended its

⁹³ Both Parties' market shares are decreasing in the vast majority of the markets listed above. The exceptions are Syphilis reagents in Greece, Hungary, Italy and Portugal, Cytomegalovirus reagents in the United Kingdom and Austria, and Chagas reagents in Italy. These markets are analysed in detail in Sections 4.3.3.1 1 to 6, with the exception of markets for Syphilis in Portugal and Chagas in Italy. For Syphilis in Portugal, the increment was below [0-5]% and the combined market share below [30-40]% in the last three years. For Chagas in Italy, the increment was below [5-10]% and the combined market share below [30-40]% in the last three years and Alere is only re-selling third party products.

⁹⁴ Alere is re-selling third party's infectious disease products in the EEA, with the exception of Syphilis in Spain and Austria, where [reference to scale] of Alere's sales is related to its own branded products. The market for Syphilis in Spain is analysed in detail in Section 4.2.2.1 2. On a market for Syphilis in Austria, Alere's market share went from less than [0-5]% in 2013 down to [0-5]% in 2015.

supply arrangement with Alere during 2015 and started to directly sell its Chagas reagent in Spain.

- (150) Post-Transaction, the merged entity will continue to face competition from well-established players in the Spanish Chagas market (Ortho Clinical: [10-20]%, DiaSorin: [10-20]%). Additional suppliers such as Werfen/IL, Siemens and Biorad also served the market in 2015.
- (151) In view of the limited increment, the nature and evolution of Alere's activities, and the remaining competitors, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to Chagas reagents in Spain.

2. Syphilis reagents and antibody assays in Spain

- (152) In 2015, the Parties' combined market share in Spain was for all Syphilis reagents [40-50]%, with an increment of [5-10]% from Alere; and for a narrower segment of Syphilis antibody assays [40-50]%, with an increment of [5-10]% from Alere. Alere [confidential] re-sold third party manufactured and labelled products from Trinity, Vircell Microbiologists, Spinreact, Sekisui and Linear Chemicals.
- (153) Post-Transaction, the merged entity will continue to face competition from well-established players in the Spanish Syphilis market (Siemens: [20-30]%, DiaSorin: [10-20]%, Roche: [5-10]%) which are all active in Syphilis antibody assays. Additional suppliers such as Fujirebio and other smaller players also served the market in 2015.
- (154) Some respondents to the market investigation indicated that there would be a degree of supply-side substitutability (meaning that one supplier active in one of the reagents could easily start being active in the others) between the supply of syphilis reagents and other infectious diseases reagents such as HIV and Rubella in particular.⁹⁵
- (155) In view of the limited increment, the nature and evolution of Alere's activities, the remaining competitors, and the results of the market investigation, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to syphilis reagents and antibody assays in Spain.

3. Syphilis reagents in the United Kingdom, Slovakia, Greece, Hungary and Italy

- (156) In 2015, the Parties' combined market share for Syphilis reagents in the United Kingdom was [30-40]%, with an increment of [0-5]% from Alere. Over the last 3 years, Alere's sales were cut by almost [percentage]. Alere [Confidential] re-sold third party manufactured and labelled reagents from Newmarket/Lab21, Zeus, Immunocell and Siemens/Dade Behring.
- (157) Post-transaction, the merged entity will continue to face competition from well-established players in the British Syphilis market (Roche: [20-30]%, Siemens: [10-20]%, Biorad: [10-20]%, DiaSorin: [5-10]%). Additional suppliers such as Werfen/IL, Trinity Biotech, bioMérieux and Grifols also served the market in 2015.

⁹⁵ Responses to Questionnaire Q1 to Competitors of 29 November 2016, question 43

- (158) Some respondents to the market investigation indicated that there would be a degree of supply-side substitutability (meaning that one supplier active in one of the reagents could easily start being active in the others) between the supply of syphilis reagents and other infectious diseases reagents such as HIV and Rubella in particular.⁹⁶
- (159) In all other countries (Slovakia, Greece, Hungary and Italy), although the combined market share exceeded 50% in at least one of the last three years, the markets were only affected but not Group 1, meaning that Alere's market share was *de minimis*, below 1%. More specifically, Alere's market share was up to a maximum of [0-5]% in Italy in 2015 and in Slovakia in 2013. In Slovakia, the market for syphilis was not even affected in 2015, meaning that the combined market share was below 20% that year.
- (160) In view of the limited increment in Slovakia, Greece, Hungary and Italy as well as the small increment, the nature and evolution of Alere's activities, the remaining competitors, and the results of the market investigation in the United Kingdom, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to syphilis reagents in the United Kingdom, Slovakia, Greece, Hungary and Italy.

4. Cytomegalovirus in the United Kingdom and in Austria

- (161) In the United Kingdom, the Parties' combined market share for cytomegalovirus was [40-50]% in 2015, with an increment of less than [0-5]% from Alere. Alere [Confidential] re-sold reagents from two manufacturers, Astra SRL and Zeus.
- (162) Post-Transaction, the merged entity will continue to face competition from well-established players in the British Cytomagalovirus market (Roche: [20-30]%, Elitech: [10-20]% and Trinity Biotech: [10-20]%). Additional suppliers such as bioMérieux, DiaSorin, Qiagen, Siemens, Werfen/IL and Biorad also served the market in 2015.
- (163) In Austria, although the combined market share of the Parties exceeded 50% in 2013 and 2015, the Transaction does not give rise to a Group 1 market in any of the last three years, since Alere's market share was *de-minimis* ([0-5]% or below in Cytomagalovirus overall and in the segment for Cytomegalovirus IgG).
- (164) In view of the limited increment in Austria as well as the small increment, the nature and evolution of Alere's activities, and the remaining competitors in the United Kingdom, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to cytomegalovirus reagents in the United Kingdom and Austria.

⁹⁶ Responses to Questionnaire Q1 to Competitors of 29 November 2016, question 43

5. *Mycobacteria in Spain, Hepatitis B Surface antibody and antigen in the United Kingdom, HIV multiple in Cyprus and the United Kingdom*

- (165) For the above-listed markets, although the combined market share of the Parties exceeded 50% in at least one of the last three years, the Transaction does not give rise to a Group 1 market in 2015.
- (166) More specifically, Alere's market shares have declined over the last three years to become very limited, namely below [0-5]%, in 2015:
- (a) from [0-5]% in 2013 to [0-5]% in 2015 for mycobacteria in Spain;
 - (b) from a maximum of [0-5]% in 2013 to [0-5]% in 2015 for hepatitis B surface antibody and antigen in the United Kingdom (in the segment limited to hepatitis B surface antigen);
 - (c) from [0-5]% in 2013 to [0-5]% in 2015 for HIV multiple in Cyprus; and
 - (d) from [0-5]% in 2013 to [0-5]% in 2015 for HIV multiple in the United Kingdom.
- (167) In view of Alere's limited market position in 2013, the overall decline of Alere's market shares leading to a limited increment (<[0-5]%) in 2015, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to mycobacteria in Spain, Hepatitis B Surface antibody and antigen in the United Kingdom, HIV multiple in Cyprus and the United Kingdom.

6. *Clostridium difficile in Spain, HIV multiple antibody in Austria, HTLV multiple antibody and Respiratory Syncytial Virus in the United Kingdom*

- (168) For the above-listed markets, although the combined market shares of the Parties exceeded 50% and led to a Group 1 market in 2013 or 2014, the Transaction does not give rise to an affected market in 2015.
- (169) More specifically, for the following markets, Alere did not have any sales in 2015 and the Transaction does not lead to horizontal overlaps in the Parties' activities any longer:
- (a) *Clostridium difficile* in Spain (no sales in 2013, nor 2015. [0-5]% market share in 2014);
 - (b) HIV multiple antibody in Austria (no sales in 2013, nor 2015. [0-5]% market share in 2014); and
 - (c) HTLV multiple antibody in the United Kingdom (no sales in 2015. Market share declined from [0-5]% in 2013 to [0-5]% in 2014).
- (170) Concerning the market for Respiratory Syncytial virus in the United Kingdom, Abbott did not have any sales in 2014 or 2015 and Alere's activities were limited to re-selling of third party manufactured products.
- (171) In view of the absence of horizontal overlaps between the Parties' activities in 2015, the Commission concludes that the Transaction does not raise serious doubts as to its

compatibility with the internal market in relation to Clostridium difficile in Spain, HIV multiple in Austria, HTLV multiple antibody and respiratory syncytial virus in the United Kingdom.

Conclusion

(172) In view of the above, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to laboratory IVD systems for infectious diseases testing.

4.3.3.2. Foreclosure effects

(a) Introduction

(173) In the laboratory sector, Alere has a contractual relationship with Danaher in relation to BNP reagents. More specifically, this relationship concerns the global manufacturing and commercialisation of BNP reagents that are compatible with Danaher's Beckman Coulter laboratory IVD systems.

(174) Alere holds a license from Scios, a company currently owned by Johnson&Johnson, according to which it has a right to manufacture and commercialise BNP reagents. Alere manufactures and commercialises BNP reagents for its own POC systems, such as the Triage, and, as it does not manufacture laboratory analysers, it cooperates with Danaher for the manufacturing and commercialisation of BNP testing in the laboratory segment.

(175) Alere concluded an exclusive manufacturing agreement ("the BCIS agreement") initially with Beckman Coulter,⁹⁷ which was subsequently acquired by Danaher. According to the BCIS agreement, Alere supplies Danaher with [Confidential detail on the BCIS agreement] antibodies [Confidential detail on the BCIS agreement].⁹⁸ Based on the raw material provided by Alere, Danaher manufactures BNP reagents compatible with its Beckman Coulter ACCESS and DXL laboratory systems, which it then sells exclusively to Alere. Alere subsequently commercialises these reagents under the Alere brand, (as Alere's BNP reagents for Beckman Coulter)⁹⁹. Both of ACCESS and DXL systems are closed systems, namely, they cannot perform the test on the basis of any other reagents than the Alere BNP reagents for Beckman Coulter

(176) In view of Abbott's presence with its ARCHITECT's systems competing with Danaher's Beckman Coulter systems, the Commission assessed whether the Transaction could give rise to any anticompetitive effects, and notably, to any foreclosure effects of the merged entity's rival, Danaher.

(177) In addition, on 30 November 2016, Danaher submitted a complaint to the Commission, as it considers that it is dependent on Alere for the supply, sale and marketing of BNP assays used in its laboratory systems ACCESS and DXL. Danaher submits that the merged entity would not be incentivised to cooperate with this arrangement post-Transaction, as –unlike Alere– Abbott has

⁹⁷ The BCIS agreement is a BNP assay development, manufacture and supply agreement between Biosite Incorporated and Beckman Coulter Inc.

⁹⁸ See Paragraph 3.1 of the BCIS agreement; Abbott's response to the Request for Information RFI I.1 of 9 December 2016, paras 57 and following.

⁹⁹ Alere Triage® BNP Test for Beckman Coulter®

competing laboratory systems from the ARCHITECT *i* and *ci* series which also include BNP in their test menu. Post-Transaction, Abbott would also get access to sensitive competitive information regarding Danaher's activities. As a result, Danaher's ability to compete in the overall IVD laboratory market (both immunochemistry and clinical chemistry analysers) and to supply customers looking for a single source of a complete product range would be restricted.¹⁰⁰

(b) Framework of assessment

- (178) A merger is said to result in foreclosure where actual or potential rival's access to supplies or markets is hampered or eliminated as a result of the merger, thereby reducing these companies' ability and/or incentives to compete. This could particularly be the case if the merged entity can foreclose access to products which are closely linked to the markets on which the companies are competing. In this case, Alere's BNP reagents are closely linked to Danaher's IVD laboratory activities where it currently competes with Abbott. Alere's BNP reagents are developed by Danaher so that they are compatible with Danaher's ACCESS and BXL analysers only; Alere does not sell any BNP reagents for use with other analysers, as this would not even be technically possible. Any change in the merged entity's commercial strategy post-Transaction in relation to the use of these reagents would therefore primarily impact Danaher.
- (179) The Commission thus assessed whether the Transaction could lead to a reduction of Danaher's ability and incentives to compete in the IVD laboratory space following a practice of the merged entity consisting in ceasing or frustrating the manufacturing and commercialisation of BNP reagents for Beckman Coulter. In assessing the likelihood of an anticompetitive foreclosure scenario, the Commission examines first, whether the merged entity would have the ability to substantially foreclose its rivals, second, whether it would have the incentive to do so, and third, whether a foreclosure strategy would have a significant detrimental effect on competition downstream.¹⁰¹

(c) Ability to foreclose Danaher

The Notifying Party's view

- (180) The Notifying Party considers that it would not have the ability to pursue any strategy foreclosing Danaher, as it is constrained by the terms of the BCIS agreement, [Confidential detail on the contractual relationship with Danaher].
- (181) In addition, even if the merged entity were to stop supplying BNP reagents for the BCIS, Danaher could source the necessary raw materials from another IVD company developing BNP antibodies or develop its own antibodies, since the Scios patent under which Alere has a license to manufacture and commercialise BNP tests expires in [Date].

¹⁰⁰ Danaher's submission of 30 November 2016 regarding the "proposed Acquisition of Alere by Abbott Laboratories"; See also an e-mail of Danaher's external counsel of 14 December 2016.

¹⁰¹ Commission Notice, Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings ("Non-horizontal Guidelines") OJ 2008/C 265/07, paras 93-94.

(182) Last, Abbott claims that a significant increase in the price of the BNP reagents for the BCIS by the merged entity, would in all likelihood be counter-productive with Alere's customers' turning in reaction to other IVD suppliers not only for BNP laboratory tests, but also for other IVD products. Moreover, such price increase would [Confidential detail on Alere's contractual relationship with Danaher].

Commission's assessment

(183) The merged entity's ability to foreclose Danaher, depends, first, on its ability to limit or interrupt the manufacturing and commercialisation of the BNP reagents for Beckman Coulter; second, on Danaher's lack of viable alternative solutions for the replacement of its current relationship with Alere; and third, on the importance of the continuous commercialisation of BNP reagents for Danaher's ability to compete on IVD laboratory markets.

(184) First, according to the BCIS agreement Alere alone determines the manufacturing volumes of BNP reagents for the BCIS, without any influence from Danaher [Confidential detail on Alere's contractual relationship with Danaher].¹⁰² Similarly, Alere alone sets the prices charged to end customers, without any required agreement by Danaher, as [Confidential detail on Alere's contractual relationship with Danaher].¹⁰³ The merged entity could therefore limit the number of reagents it orders from Danaher, thus making sourcing of BNP reagents difficult for Danaher's ACCESS and DXL customers, or materially increase their price, thus making them less attractive. Moreover, in light of the explicit provision in the BCIS agreement that the pricing of the BNP reagents is decided exclusively by Alere, [Confidential detail on Alere's contractual relationship with Danaher]. Moreover, given Alere's limited activities in the laboratory space and the fact that BNP reagents are not linked to other product sales by Alere, any retaliation by customers would also be unlikely.

(185) Second, in the framework of the BCIS agreement, [Confidential detail on Alere's contractual relationship with Danaher].¹⁰⁴ As a result, as long as the BCIS agreement is in place, Danaher relies on Alere (and in the future on the merged entity) for the manufacturing and commercialisation of BNP reagents that may be used on its analysers.¹⁰⁵ Danaher can terminate the BCIS agreement [Confidential detail on Alere's contractual relationship with Danaher]. Therefore, if the merged entity were to pursue a strategy aiming at Danaher's foreclosure, Danaher would not be in the position of unilaterally developing, manufacturing or selling its own BNP reagents.

(186) Moreover, even if Danaher were relieved from the obligation to [Confidential detail on Alere's contractual relationship with Danaher], it could not develop and commercialise its own reagents or easily replicate the relationship it currently has with Alere. The manufacturing of BNP reagents is currently patent-protected and Danaher does not hold any license allowing it to use that patent. Danaher would therefore have to either develop its own BNP reagents, or source BNP reagents from other possible suppliers.

¹⁰² BCIS Agreement, para 5.3.

¹⁰³ Exhibit B to the BCIS Agreement, para 3.3.

¹⁰⁴ BCIS Agreement, paras 5.2.1 and 5.2.3.

¹⁰⁵ According to 5.2.3 of the BCIS agreement, Danaher would be [Confidential detail on Alere's contractual relationship with Danaher]; Abbott's response to RFI I.1 of 9 December 2016, question 6.

- (187) As to the development of own reagents by Danaher, Abbott submits that it would require approximately [duration] and an investment of USD [estimation of amount].¹⁰⁶ Yet, the initial development of the BNP reagents for the BCIS by Alere, under its Scios license, required [duration] years. Moreover, even if Danaher had access to the Scios patent for the manufacturing of BNP reagents, it would still in addition need access to raw materials, such as the antibodies and proteins it currently sources from Alere, and it would have to acquire the CE mark and register the newly developed reagent across the EEA. This process is therefore likely to require significant time and investment, during which Danaher would not be able to seek new customers for its BNP testing and Danaher's existing customers would not be able to source BNP reagents for the BCIS.
- (188) Furthermore, replicating the relationship it currently has with Alere with some other provider of BNP reagents would also not be simple for Danaher, as IVD companies already active in BNP laboratory testing would not necessarily be willing to enter into such cooperation with Danaher and as adjustments would again be required in order to ensure compatibility with Danaher's ACCESS and DXL analysers.
- (189) In light of the above considerations, the Commission concludes that the merged entity could significantly limit, terminate or render very costly the supply of BNP reagents for the BCIS in the EEA, without Danaher being able to effectively react to such strategy, either under the BCIS contract or by ensuring the development and commercialisation of other BNP reagents that are compatible with its analysers, individually or in cooperation with third parties. Therefore, the merged entity would have the ability to foreclose Danaher in a way that could limit Danaher's ability to compete on markets for laboratory analysers or systems and potentially also result to its exit from these markets.

(d) Incentive to foreclose Danaher

- (190) The incentive to foreclose rivals depends on the degree to which this strategy is profitable. The merged entity faces a trade-off between, on one hand, the possible costs associated and any potential losses of customers through such strategy and, on the other hand, the possible gains from expanding market shares or from being able to raise prices in the markets concerned.¹⁰⁷

The Notifying Party's view

- (191) The Notifying Party considers that the merged entity will not have an incentive to foreclose Danaher since the downstream sale of the BNP reagents by Alere generated [...] sales of approximately EUR [Amount] in 15 EEA Contracting Parties,¹⁰⁸ with high profits margins ranging from [estimated profitability]%.
- (192) The Notifying Party adds that since the laboratory analysers of Abbott are closed, the merged entity could not shift its revenue from the sale of Beckman Coulter BNP reagents to Abbott BNP reagents on its ARCHITECT analysers.

¹⁰⁶ Abbott's response to RFI I.1 of 9 December 2016, question 6.

¹⁰⁷ Non-horizontal Guidelines, paras 105-110.

¹⁰⁸ Belgium, Czech Republic, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden and the United Kingdom.

- (193) The Notifying Party also indicates that the merged entity cannot reasonably expect an increase of sales of Abbott's ARCHITECT analysers to new customers switching from Danaher Beckman Coulter by more than Alere's BNP sales of [Confidential]. The Notifying Party argues that such an increase of sales would be unlikely in particular there is [Confidential].

The Commission's assessment

- (194) First, to determine whether Abbott has an incentive to follow a foreclosure strategy, the Commission analyses whether frustrating the BNP reagents' supply (by not supplying them or increasing their prices) in the Beckman Coulter analysers would affect Danaher's position in the IVD laboratory sector to the benefit of competitors such as Abbott. Danaher's position could be affected for instance if, in that case, its analysers became less attractive to new customers or if its current customers may switch to a competing analyser offering BNP reagents.
- (195) BNP testing, together with NT-proBNP testing, appears to be an important feature of immunochemistry IVD laboratory analysers. The two tests are used for the detection, diagnosis and evaluation of the severity of heart failure. The market investigation indicated that there is no alternative to BNP and NT-proBNP testing and that customers are in principle interested in sourcing one of the two.¹⁰⁹ Moreover, the European Society of Cardiology recommends that a BNP or NT-proBNP test is performed to all patients presenting related symptoms.¹¹⁰ The majority of customers responding to the market investigation also submit that all the immunochemistry systems they purchase perform BNP/NT-proBNP tests and some customers specifically indicate that they would switch systems, if their BCIS analysers no longer offered BNP testing.¹¹¹
- (196) Therefore, it cannot be excluded that Danaher's current customers would switch to other competitors, not only for the specific BNP reagent, but for an entire and different immunochemistry system or integrated system (including both immunochemistry and clinical chemistry). Similarly, Danaher's inability to provide BNP tests could impact its capacity to compete for new customers. The merged entity could therefore benefit from Danaher's loss of business not only in relation to BNP reagents, but more broadly in the immunochemistry or even, in the entire IVD LAB sector altogether.
- (197) Second, to assess whether the merged entity would have an incentive to foreclose Danaher, the Commission analyses whether such strategy would be profitable. To that end, a first comparison should be made on a country-by-country basis between the profits generated by the sales of Alere's BNP reagents for the BCIS and which the merged entity would sacrifice; and the additional profit it would conversely

¹⁰⁹ The market investigation showed that BNP and NT-proBNP are interchangeable, but also differentiated. They are both used for the detection, diagnosis and evaluation of the severity of heart failure in short time; See Responses to Questionnaire Q2 to Customers of 29 November 2016, questions 38 to 40; Abbott's response to RFI I.1 of 9 December 2016, para 100.

¹¹⁰ 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure, European Heart Journal (2016) 37, p.2176: "*Upon presentation a measurement of plasma natriuretic peptide level (BNP, NT-proBNP or MR-proANP) is recommended in all patients with acute dyspnoea and suspected AHF to help in the differentiation of AHF from non-cardiac causes of acute dyspnoea.*";

¹¹¹ Responses to Questionnaire Q2 to Customers of 29 November 2016, question 38.3 and 44

capture through increased sales of its laboratory ARCHITECT systems (analysers and reagents) as a consequence of Danaher's exit of the laboratory market.

- (198) In that respect, the Notifying Party's general reasoning as explained above has the following main limitations:
- (a) Its incentive assessment is done at the aggregate level of 15 EEA Contracting Parties and not per relevant country; and
 - (b) It only takes into account the share of profits the merged entity would gain on the BNP reagents sales and not on the overall laboratory systems.
- (199) Based on the information provided by the Parties¹¹² and assuming that (i) Danaher fully exits the market of laboratory analysers which can perform BNP and/or NT-proBNP tests ("BNP LAB analysers") and that (ii) the remaining market participants (in particular Abbott) capture Danaher's profit proportionally to their respective market shares on the remaining market for BNP LAB analysers, the Commission finds that a foreclosure strategy by the merged entity would be profitable at least in Norway and in the Czech Republic. If we further consider, as can be reasonably expected, that as a result of Danaher's exit from the market and the consequent decrease of competitive pressure exerted on the merged entity in a more concentrated oligopolistic market, the latter could increase the reagents on BNP LAB analysers sales price by 5%, the merged entity would additionally have an incentive to foreclose Danaher in Poland, the United Kingdom, Spain and in Sweden.
- (200) In that respect it should also be noted that the assumption that Abbott would capture a part of Danaher's customer base proportional to its current market share is rather conservative. Indeed, as Alere frequently coordinates its BNP reagents' sales with Alere, it has good knowledge of Danaher's sales practices and customer base, which it could leverage in order to compete more effectively for end users formerly buying Danaher's analysers. If Abbott were to capture a more than proportional share of Danaher's customer base, the foreclosure strategy would remain profitable, even without having to assume Danaher's full exit from the laboratory analysers market.
- (201) In addition, in some countries, the trade off the merged entity will face is not only between its profits on BNP reagents sales to Beckman Coulter analysers versus additional profits on its laboratory systems, but also a risk of losing Abbott's current profits if it decides to continue supplying Danaher. Indeed, the regulatory framework applicable to IVD tenders in Spain, for instance, foresees that a company may only participate with one bid in a given tender. So far, [Confidential detail on Alere's contractual relationship with Danaher].¹¹³ Post-Transaction, if the merged entity wants to respond to a tender for the entire systems, it would automatically exclude the participation of Danaher. On one hand, Danaher would not be in the position of including BNP reagents in its bid, whereas on the other hand, the merged entity would be prohibited from jointly bidding with Danaher, as long as it would want to submit another bid of its own.¹¹⁴

¹¹² Abbott's response to RFI I.1 of 9 December 2016, Table 3, Annex 4 and Annex 6.

¹¹³ Abbott's response to RFI I.1 of 9 December 2016, para 38

¹¹⁴ See Annex 6.11.2.8 to the Form CO, p.2; Abbott's response to the RFI I.1 of 9 December 2016, question 15.

(202) Therefore, implementing a strategy through which the commercialisation of BNP reagents would be frustrated, would likely have an exclusionary effect and be profitable for the merged entity, at least in some countries. Therefore, the merged entity would have the incentive to foreclose Danaher.

(e) Effects of Danaher's foreclosure

The Notifying Party's view

(203) The Notifying Party submits that such foreclosure strategy would in any event not have any effect on markets for the supply of immunochemistry devices, as a large number of alternative large suppliers are active on that market and would continue exerting competitive pressure on the merged entity. A price increase for end-customers can therefore not be expected.¹¹⁵

The Commission's assessment

(204) In light of the significance of the inclusion of BNP in IVD laboratory systems and as developed above, it cannot be excluded at this stage of the investigation that the merged entity's foreclosure strategy could result in Danaher having to exit the, already significantly concentrated, IVD laboratory markets for immuno-chemistry testing and possibly for clinical and immunochemistry testing.¹¹⁶

(205) The IVD laboratory markets for immuno-chemistry testing and possibly for clinical and immunochemistry testing are rather concentrated in the EEA, with 3 significant players, namely Roche, Siemens and Abbott, representing 60-70% of the total market.¹¹⁷ At national level, the market share of Danaher can reach up to [10-20]%. A further concentration of the market in case of Danaher's exit could thus result in price increases and reduction of choice for the end customers.

(206) Some competitors responding to the market investigation have also echoed the foreclosure concern of Danaher and identified potential negative effects of the Transaction in relation to BNP reagents, mainly consisting in price increases.¹¹⁸

(207) In light of all available evidence, the Commission considers that if the merged entity were to engage in an exclusionary strategy foreclosing Danaher, such practice would likely lead to a merger-specific anti-competitive effect.

(f) Conclusion

(208) The Commission therefore considers at this stage of its investigation that the Transaction raises serious doubts as to its compatibility with the internal market due to its likely foreclosure effects that could allow the merged entity to profitably increase the price charged to consumers, in relation to IVD laboratory immunochemistry testing in the EEA, and in particular in Norway, Czech Republic,

¹¹⁵ Abbott's response to the RFI I.1 of 9 December 2016, para 17.

¹¹⁶ This would be the case, irrespective of the precise delineation of the product market for IVD laboratory testing, namely irrespective of whether broader markets for IVD laboratory systems or narrower markets for IVD laboratory analysers and IVD laboratory reagents are considered.

¹¹⁷ Abbott's response to the RFI I.1 of 9 December 2016, Annex 6.

¹¹⁸ Responses to Questionnaire Q1 to Competitors of 29 November 2016, question 52.

Poland, the United Kingdom, Spain, Sweden, Germany, and Slovenia in particular.¹¹⁹

5. PROPOSED REMEDIES

- (209) For the reasons set out above, the Commission concludes that the notified operation gives rise to serious doubts as regards its compatibility with the internal market, resulting from:
- (a) the horizontal overlaps between the Parties' activities in the markets for POC blood gas systems (and the possible narrower segment for handheld systems only) in the human and veterinary spaces and for POC cardiac markers systems in the EEA in general and in the EEA Contracting Parties listed in paragraphs (93), (103) and (121) above in particular; and
 - (b) the vertical relationship between Alere and Danaher in relation to the manufacturing and commercialisation of BNP reagents in the EEA in general and in EEA Contracting Parties listed in paragraphs (208) above in particular.
- (210) In order to remove the serious doubts resulting from the Transaction, Abbott formally submitted Commitments to the Commission on 4 January 2017 (referred to as "Initial Commitments" in this Decision). The Commitments were modified on 19 January 2017 (referred to as "Final Commitments" in this Decision). The proposed Final Commitments are annexed to this Decision and form an integral part thereof.

5.1. Framework for the assessment of the Commitments

- (211) Where the Commission finds that a concentration raises competition concerns in that it could significantly impede effective competition, in particular as a result of the creation or strengthening of a dominant position, the Parties may seek to modify the concentration in order to resolve the competition concerns and thereby gain clearance of their merger.¹²⁰
- (212) Under the Merger Regulation, it is the responsibility of the Commission to show that a concentration would significantly impede effective competition. The Commission then communicates its competition concerns to the parties to allow them to formulate appropriate and corresponding remedies proposals. It is then for the parties to the concentration to put forward commitments.¹²¹ The Commission only has power to accept commitments that are deemed capable of rendering the concentration compatible with the internal market so that they will prevent a significant impediment of effective competition in all relevant markets where competition concerns were identified.¹²² To this aim, the commitments have to eliminate the

¹¹⁹ In light of Section 4.3.3.2 (d), these are the EEA Contracting Parties, to which a foreclosure strategy would at this stage of the analysis and on the basis of the submitted evidence; appear to be profitable to the merged entity.

¹²⁰ Commission notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "Remedies Notice"), OJ 2008/C 267/01, para 5.

¹²¹ Remedies Notice, para 6.

¹²² Remedies Notice, para 9

competition concerns entirely¹²³ and have to be comprehensive and effective from all points of view.¹²⁴

- (213) In assessing whether the proposed commitments will likely eliminate the competition concerns identified, the Commission considers all relevant factors including *inter alia* the type, scale and scope of the proposed commitments, judged by reference to the structure and particular characteristics of the market in which the competition concerns arise, including the position of the Notifying Party and other participants on the market.¹²⁵
- (214) In order for the commitments to comply with these principles, commitments must be capable of being implemented effectively within a short period of time.¹²⁶ Where, however, the Notifying Party submits remedies proposals that are so extensive and complex that it is not possible for the Commission to determine with the requisite degree of certainty, at the time of its decision, that they will be fully implemented and that they are likely to maintain effective competition in the market, an authorisation decision cannot be granted.¹²⁷ The requisite degree of certainty concerning the implementation of the proposed commitments may in particular be affected by risks in relation to the transfer of a business to be divested.¹²⁸
- (215) Commitments in Phase I can only be accepted where the competition concerns are readily identifiable and can be easily remedied. The remedies need to be so clear-cut that it is not necessary to enter into an in-depth investigation as to whether they are sufficient to rule out 'serious doubts' within the meaning of Article 6(1)(c) of the Merger Regulation.¹²⁹
- (216) As concerns the form of acceptable commitments, the Merger Regulation leaves discretion to the Commission as long as the commitments meet the requisite standard.¹³⁰ In general structural commitments are the best way to eliminate competition concerns resulting from horizontal overlaps.
- (217) In this regard divested activities must consist of a viable business that, if operated by a suitable purchaser, can compete effectively with the merged entity on a lasting basis and that is divested as a going concern.¹³¹ Normally, a viable business is a business that can operate on a stand-alone-basis, which means independently of the merging parties as regards the supply of input materials or other forms of cooperation other than during a transitory period.¹³² The Commission has a clear

¹²³ See also Case C-202/06 *P Cementbouw Handel & Industrie v Commission* [2007] ECR 2007 I-12129, para 54

¹²⁴ Remedies Notice, paras 9 and 61

¹²⁵ Remedies Notice, para 12

¹²⁶ Remedies Notice, para 9

¹²⁷ Remedies Notice, paras 13, 14 and 61

¹²⁸ Remedies Notice, para 11

¹²⁹ Remedies Notice, para 81

¹³⁰ Case T-177/04, *EasyJet v Commission* [2006] ECR II-1913, para 197: "*Article 6(2) of Regulation No 4064/89 provides that the Commission may authorise a merger if the commitments proposed by the parties dispel the serious doubts as to the compatibility of the merger with the common market. Regulation No 4064/89 thus lays down the objective to be achieved by the Commission, but leaves it a wide discretion as to the form which the commitments in question may take.*"

¹³¹ Remedies Notice, para 23

¹³² Remedies Notice, para 32

preference for an existing stand-alone business. In proposing a viable business for divestiture, it is necessary to take into account the uncertainties and risks related to the transfer of a business to a new owner. These risks may limit the competitive impact of the divested business, and, therefore, may lead to a market situation where the competition concerns at stake will not necessarily be eliminated.¹³³

- (218) While divested businesses should in principle contain all tangible assets including manufacturing assets which contribute to its current operation¹³⁴, carve out of manufacturing assets may be acceptable only exceptionally in very specific circumstances if their workability is fully ensured by effective implementation and monitoring.¹³⁵ A divestiture consisting of a combination of certain assets which did not form a uniform and viable business in the past creates risks as to the viability and competitiveness of the resulting business. In such circumstances, the package must be sufficient to allow the Commission to conclude that the resulting business will be immediately viable in the hands of a suitable purchaser.¹³⁶
- (219) It is against this background that the Commission assessed the viability, the workability, the effectiveness and the ability of the proposed commitments to entirely eliminate the competition concerns identified.

5.2. Description of the Initial Commitments

- (220) The Initial Commitments related to the horizontal overlaps consist in the divestiture of Alere's EPOC (the *EPOC Divestment Business*) and Alere's Triage (the *Triage Divestment Business*) businesses at global level.
- (221) As to the foreclosure concern, the Initial Commitments provide for two alternatives commitments: either (i) to negotiate an end to the BCIS agreement with Danaher, enabling the latter to independently commercialise the BNP assays and supply the BNP antibodies in the EEA; or (ii) as an alternative, to divest the BCIS agreement with Danaher to a purchaser, including a production transfer for the BNP antibodies and raw materials (the *Beckman Divestment Business*).
- (222) In view of inter alia the need to get third party consents (in particular from Scios holding IP rights in BNP for POC and laboratory uses), the Initial Commitments contain an upfront buyer provision.

¹³³ Remedies Notice, para 24

¹³⁴ Remedies Notice, para 25-27

¹³⁵ Remedies Notice, para 17

¹³⁶ Remedies Notice, para 37

The EPOC and Triage Divestment Businesses in the Initial Commitments

- (223) As to the EPOC and Triage Divestment Businesses, the Initial Commitments consist in the divestment of the manufacturing, development and commercialisation of the EPOC and Triage systems globally, comprising both analysers and reagents.
- (224) The EPOC Divestment Business (which covers the EPOC system for both human and veterinary uses) comprises the EPOC production and R&D site at Ottawa (Canada), together with the personnel and inventories. It further includes the main following assets:
- all patents used for the EPOC system and all licenses and rights in intellectual property (either through a transfer/assignment for the ones exclusively and predominantly used for EPOC or through an irrevocable perpetual royalty free license for the other ones);
 - all necessary trademarks (except "Alere") and all trade secrets, confidential know-how, confidential customer data related to the EPOC system (either through a transfer for the ones exclusively and predominantly related to the EPOC system or co-ownership of undivided interest with Alere for the others);
 - all regulatory clearances and authorisations;
 - all advertising, marketing, training and promotional materials;
 - all necessary contracts related to EPOC (including but not limited to customers contracts, lists, information and history, supply contracts, building lease contracts, all third party distribution contracts, R&D agreements); and
 - all pipelines related to the EPOC system (through a transfer for the pipelines exclusively or predominantly related to EPOC or an access for the other ones).
- (225) The Triage Divestment Business consists in parts of the manufacturing and R&D facility located in San Diego (United States), where the Triage system is currently manufactured (two buildings out of the four buildings of the plant, together with the personnel and inventories in these buildings). It further includes the main following assets:
- all patents used for the Triage system and all licenses and rights in intellectual property (either through a transfer/assignment for the ones exclusively and predominantly used for Triage or through an irrevocable perpetual royalty free license for the other ones);
 - all trademarks (except "Alere") and all trade secrets, confidential know-how, confidential customer data related to the Triage system (either through a transfer for the ones exclusively and predominantly related to the Triage system or co-ownership of undivided interest with Alere for the other ones);
 - all regulatory clearances and authorisations, except the manufacturing license under which the Triage system and other Alere products are manufactured in the San Diego site which would be made available to the

purchaser (until it is able to obtain its own manufacturing license for the manufacture of Triage);

- all advertising, marketing, training and promotional materials;
- all contracts related to Triage (including but not limited to customers contracts, lists, information and history, supply contracts, all third party distribution contracts, manufacturing contracts, all packaging agreements and R&D agreements); and
- any pipelines related to the Triage system (through a transfer for the pipelines exclusively or predominantly related to Triage or an access for the other ones).

- (226) The Initial Commitments foresee transitional services agreements between the merged entity and the Purchaser of the Triage Divestment Business for the respective use of parts of the divested and retained buildings in San Diego until the necessary transfers are finalised. The Initial Commitments also foresee a post-transitional period lease between the merged entity and the Purchaser for the use of part of one building dedicated to reagent production, general assembly, the Ionian operation and warehouse space, amounting to 48% of the entire building use.
- (227) The Triage Divestment Business also explicitly excludes: (i) the personnel and assets located in the parts of the manufacturing plant to be divested which do not relate to the Triage System, and (ii) the antibody generation and reagent formulation which support the Triage System (notably for BNP), but also other products of Alere. Abbott committed to supply them to the purchaser on a transitional basis.

The Beckman Divestment Business in the Initial Commitments

- (228) The Beckman Divestment Business consists in two alternatives.
- (229) The first alternative consists in a commitment for Abbott to use all reasonable best endeavours to agree with Danaher on reasonable terms and conditions for a structured exit from the BCIS agreement. At the end of the exit period, Danaher would not be dependent on the merged entity for the European commercialisation of the BNP assays for the BCIS or the supply of the BNP antibodies and would have the ability to produce BNP antibodies and commercialise BNP assays in Europe on its own account. The merged entity would have no direct or indirect control or influence over the pricing or volumes of BNP assays commercialised by Danaher.
- (230) The second alternative consists in the divestiture of the BCIS agreement to a third party. The Beckman Divestment Business consists in the supply of BNP antibodies to Danaher and the commercialisation of BNP assays (together with the personnel required for such commercialisation and inventories). It further includes the main following assets:
- a transitional manufacturing and supply agreement as well as a technology transfer to the purchaser on the corresponding supply obligations to Danaher under the BCIS agreement, including a right or license to use the trade secrets, confidential know-how, other confidential information and certain intellectual property to the extent used in the manufacture of the BNP antibodies for Danaher pursuant to the BCIS agreement;

- any other relevant licenses necessary following the expiration of the transitional supply and technology transfer, through assignment of an irrevocable perpetual royalty free;
- all trademarks (except "Alere" or any trademark relating to the Triage Divestment Business), and all trade secrets, confidential know-how, confidential customer data and certain other intellectual property rights (either through a transfer for the ones exclusively or predominantly related to the Beckman Divestment Business or co-ownership of undivided interest with Alere for the other ones);
- all regulatory clearances and authorisations;
- all advertising, marketing, training and promotional materials;
- all contracts related to the BCIS agreement (including customers contracts, lists, information and history, supply contracts, all distribution agreements).

(231) The Beckman Divestment Business also includes a possibility to hire personnel providing customer services, distribution or sales and marketing services and personnel who manufacture BNP antibodies after the expiration of the transitional supply and technology transfer.

(232) The Beckman Divestment Business explicitly excludes however: (i) the personnel, tangible and intangible assets required for the manufacture and commercialization of Triage or other Alere products and (ii) the antibody generation and reagent formulation and manufacturing operations at the San Diego site, which support Triage and many other Alere products.

The Purchaser criteria

(233) In the Initial Commitments, in addition to requirements on independence vis-à-vis the merged entity, financial capabilities, proven expertise, ability and incentives to run the Divestment Business as a viable and competitive force and the absence of prima facie competitive concerns and implementation risks, each Purchaser shall have an established presence, including distribution and sales capabilities in the IVD sector.

5.3. Results of the market test of the Initial Commitments

(234) The market test of the Initial Commitments was launched on 6 January 2017. Overall, the results of the market test were positive for the EPOC Divestment Business, while in relation to the Triage Divestment Business and the Beckman Divestment Business market participants identified complexities, entanglements and implementation risks that would make their implementation complex and would not guarantee viability and competitiveness in the hands of a suitable purchaser.

5.3.1. The EPOC Divestment Business

(235) The results of the market test, both for competitors and customers of Abbott and of Alere, indicated that no material or immaterial assets were missing from the

proposed divestment for a successful transfer of the EPOC business to the Purchaser.¹³⁷

- (236) Customers confirmed that they would be willing to purchase EPOC systems if acquired by an appropriate buyer, that is, a company already active in the IVD sector with a substantial footprint.¹³⁸
- (237) The market test did not identify significant implementation risks.

5.3.2. The Triage and Beckman Divestment Businesses

- (238) The results of the market test indicated that the Triage and Beckman Divestment Businesses as foreseen in the Initial Commitments contain some limitations, which may put into question the viability and effectiveness of the divestments.
- (239) As to the Triage Divestment Business, respondents to the market test insisted on the importance of having control of the full Triage system supply chain, including control over the whole manufacturing plant and key raw materials.
- (240) In that respect, several respondents, firstly identified the San Diego plant sharing, transitional services and also the envisaged leasing of part of one building by the merged entity, as creating complexities and entanglements for the Purchaser, affecting the viability of the divestment.¹³⁹ One market respondent specified for instance that "*the business to be divested is not standalone e.g. shared services for manufacturing, and this may make it difficult to make long term plans and run the business*".¹⁴⁰
- (241) Secondly, several respondents also identified risks in not having control over the antibody generation, reagent formulation and manufacturing operations, which support the Triage system and reagents.¹⁴¹ Competitors convincingly stated that for the viability and ability to compete of the Triage Divestment business the antibody generation and reagent formulation of all of the Triage platform products at the San Diego plant would need to be transferred to the Triage Divestment Business. One competitor explained that "*these tasks are vital for keeping the products on available for the customers. In case there are quality, availability problems the consequences for the acquirer are immediately intense*".¹⁴² Respondents also identified the risk associated with a production transfer of the antibody generation and reagent formulation to another plants owned by the Purchaser. One player indicated that "*transferring production to own capabilities would create a huge risk. Normally, IVD players try to avoid switching antibody generation during the lifetime of a product*".¹⁴³ On the customers' (hospitals) side, it is clear that the Triage Divestment

¹³⁷ Responses to Questionnaire R2 to Customers of 6 January 2017, question 2 and responses to Questionnaire R1 to Competitors of 6 January 2017, question 2

¹³⁸ Responses to Questionnaire R2 to Customers of 6 January 2017, questions 3 and 3.1

¹³⁹ Responses to Questionnaire R1 to Competitors of 6 January 2017, questions 22 and 23

¹⁴⁰ Response of a competitor to Questionnaire R1 to Competitors of 6 January 2017, question 23.1

¹⁴¹ Responses to Questionnaire R1 to Competitors of 6 January 2017, questions 25 and 25.1; See namely the response of a competitor to Questionnaire R1 to Competitors of 6 January 2017, question 25.1: "*Lack of control over value chain*"

¹⁴² Response of a competitor to Questionnaire R1 to Competitors of 6 January 2017, question 25.1

¹⁴³ Response of a competitor to Questionnaire R1 to Competitors of 6 January 2017, question 25.1

Business has to be able to continue supplying the critical BNP and Troponin reagents in the Triage system.¹⁴⁴

- (242) As to the Beckman Divestment Business, the majority of responding competitors also believed that a technology transfer of the BNP antibodies to the purchaser, which would have to then use own manufacturing facilities and personnel, entails significant implementation risks for the Beckman Divestment Business.¹⁴⁵ The viability chances of the Beckman Divestment Business would then heavily depend on the acquirer's knowledge, experience and ability to successfully execute the technology transfer of the antibodies.¹⁴⁶
- (243) Finally, as to the purchaser requirements, there is a clear indication in the market test that customers would prefer for the purchaser of the Triage Divestment Business and the Beckman Divestment Business to be active in the IVD space commercializing complementary products.¹⁴⁷
- (244) In view of the above, the results of the market test identified risks on the viability and competitiveness of the Triage and Beckman Divestment Businesses as foreseen in the Initial Commitments.

5.4. Description of the Final Commitments

- (245) Taking into account the market test results, the Parties submitted the Final Commitments including several major improvements for the Triage and Beckman Divestment Businesses.
- (246) First, the Final Commitments include in the Triage Divestment Business the entire San Diego manufacturing facility and provide for a reverse carve-out for the manufacturing businesses of the other, unrelated Alere products, currently in that site, namely Cholestech LDX Analyser, visual read DOA panels and the visual read micro parasite panels.
- (247) The Triage Divestment Business therefore includes all the antibody generation and reagent formulation, the manufacturing equipment and personnel, which supports the Triage system.

¹⁴⁴ Responses to Questionnaire R2 to Customers of 6 January 2017

¹⁴⁵ Responses to Questionnaire R1 to Competitors of 6 January 2017, questions 48 and 48.1, see namely the response of a competitor to question 48.1: "*transferring manufacturing is always a risk / a challenge in IVD*"; See also the responses of four other competitors to Questionnaire R1 to Competitors of 6 January 2017, question 48.1: "*There always risks unless all is transferred*", "*Antibody manufacturing transfer is complex*", "*Implementation risks are always present when there is a change in the manufacturing site.*", "*The transfer of a manufacturing license and obtaining regulatory approval in the cardiac market is a difficult process*".

¹⁴⁶ Responses to Questionnaire R1 to Competitors of 6 January 2017, questions 52 to 53.2.1; See namely the response of a competitor to Questionnaire R1 to Competitors of 6 January 2017, question 52: "*Experience and expertise in the full value chain operations of critical IVD markers. Also the knowhow should include the manufacturing of the antibodies*".

¹⁴⁷ Responses to Questionnaire R2 to Customers of 6 January 2017, questions 15 to 15.2.1 and 18 to 18.2.1; See namely the response of a customer to Questionnaire R2 to Customers of 6 January 2017, question 18.1.1: "*The presence in the IVD diagnostic area in terms of marketing, experience and customers is remarkable aspect to be an fully active competitor ,in the case of Beckman Divestment Business only companies already present in the market may have interest in [...] this business*"

- (248) The Triage Divestment Business also includes the manufacturing and supplying to Danaher of the BNP Antibodies used in the manufacture by Danaher of the BNP reagents (the "**BC Manufacturing Activities**").
- (249) To address the foreclosure concern, the Final Commitments provide for the divestment of Alere's business for the commercialization of BNP reagents in BCIS (the "**BC Commercialization Divestment Business**") which can be sold either to the same purchaser as the Triage Divestment Business, or to a different purchaser. Instead of having a specific commitment in relation to possible negotiation directly with Danaher, by not limiting the scope of potential purchasers, Danaher could acquire the BC Commercialization Business to obtain full control over the commercialization of BNP reagents in its analysers.
- (250) The Final Commitments leave open the possibility of having three different purchasers for each of the Divestment Businesses. However, there will be links between the purchasers; the purchaser of the Triage Divestment Business will supply the BNP antibodies to Danaher, used to manufacture the BNP reagents which will be commercialized potentially by another purchaser. Having two different purchasers of the Triage and BC Commercialisation Businesses would also require Scios to agree in [Confidential detail on Alere's licence agreement with Scios]. In addition, while the EPOC and Triage systems are complementary POC IVD systems,¹⁴⁸ the Final Commitments leave open the possibility of having separate purchasers for the EPOC system and for the Triage system but requests that each purchaser shall have an established presence in the IVD sector with complementary products. Consequently, in view of all the possible interactions between the three divestments, the Final Commitments provide that:
- (a) the approval of the proposed purchaser(s) will only be given by the Commission after having assessed the complete information and received the agreements concluded in relation to all three divestments so as to be able to make an overall assessment of the purchaser(s)' suitability;
 - (b) Abbott shall bring satisfactory evidence that the Purchaser has obtained the consents of Scios and any other critical intellectual property rights' holders for the transfer of the relevant licenses and/or use of the relevant other IP rights for such approval(s).
- (251) As was the case already the initial commitments, in view of inter alia the need to get third party consents, in particular the transfer of contracts and IP rights in BNP for POC and laboratory uses and as the identity of the purchasers may be key to the viability of the divestment businesses, the Final Commitments contain an upfront buyer provision.
- (252) The full description of the assets and obligations of the Final Commitments is contained in the Schedule thereof.

¹⁴⁸ Responses to Questionnaire R1 to Competitors of 6 January 2017, question 42.1, see namely the response of a competitor: "*They are in many countries nicely overlapping in the same customer group or purchasing process. Especially in many of the smaller EU countries, it is the same salesforce selling them both.*"; See also the responses of two other competitors to Questionnaire R1 to Competitors of 6 January 2017, question 42.1: "*yes usually same customers in the hospital*" and "*same customer base*".

5.5. Overall assessment of Final Commitments

5.5.1. *Scope of the Final Commitments and their suitability to remove identified concerns*

- (253) As explained in this Decision, the serious doubts as to the compatibility of the Transaction with the internal market reside in the combination of Abbott and Alere's activities in POC blood gas systems for human and veterinary use and POC cardiac markers systems for human use, and in the likely foreclosure effects arising from the BCIS agreement between Alere and Danaher.
- (254) The Final Commitments consist in the divestment of both of the Alere's EPOC and Triage systems representing the full horizontal overlap between the Parties as regards POC blood gas and POC cardiac markers systems in the EEA.
- (255) The Final Commitments also consist in the divestment of the BNP antibodies manufacturing assets and activities within the Triage Divestment Business as well as in the divestment of the commercialisation of BNP reagents for the BCIS. These represent the full commercial relationship between Alere and Danaher, which gave rise to the risk of foreclosure post-Transaction.
- (256) More specifically, the Divestment Businesses include all tangible and intangible assets necessary for their on-going activities. In particular, the full supply chain, including all necessary equipment, manufacturing facilities, personnel, R&D, distribution, product pipelines, IP rights and trademarks as described in the Commitments schedules A, B and C have been included in the Divestment Businesses.
- (257) The Divestment Businesses are worldwide in scope. They include for the EPOC and Triage businesses, the facilities in Ottawa and San Diego which are the sole production sites globally. The BC Commercialisation Divestment Business also covers the worldwide commercialisation of BNP reagents for BCIS to customers of Danaher.
- (258) On this basis, the Commission considers the Final Commitments to be sufficient in scope and suitable to remove the serious doubts as to the compatibility of the Transaction with the internal market.

5.5.2. *Viability and likelihood of effectiveness of the Final Commitments in practice*

5.5.2.1. The EPOC Divestment Business

- (259) Based on the Parties' information, the EPOC Divestment Business generated [Confidential detail on revenues generated from EPOC Divestment Business] in 2016 with a gross margin of [Confidential detail on gross margin of EPOC Divestment Business] and leading to a CAGR of [Confidential detail on CAGR of EPOC Divestment Business] since 2013. EBITDA has [Confidential detail on EBITDA of EPOC Divestment Business], mainly because of significant investments into new manufacturing lines and into [Confidential detail on Alere's EPOC business] provides the EPOC Divestment Business with important potential for future growth leading [Confidential detail on EBITDA of EPOC Divestment Business]. Synergies on certain fixed costs (such as tax, treasury, legal services and general IT support and maintenance) are also achievable by a Purchaser already

well-established in the IVD field and should further improve the profitability of the EPOC Divestment Business. The market test has confirmed the attractiveness of the EPOC Divestment Business.

- (260) The EPOC Divestment Business covers all the assets and personnel of Alere in the market for POC blood gas testing for human and veterinary uses, including all pipeline products. No activities are carved out from the Ottawa plant, and no products currently manufactured in that plant are retained by the merged entity.
- (261) On this basis, the Commission considers that the EPOC Divestment Businesses as set out in the Final Commitments, constitute a viable business with a well-positioned portfolio product covering the entire value chain, in order to be able to effectively compete on the IVD market for POC blood gas on a lasting basis.

5.5.2.2. The Triage Divestment Business

- (262) In 2015, the Triage Divestment Business generated [Confidential detail on revenues generated from Triage Divestment Business] with a gross margin of [Confidential detail on gross margin of Triage Divestment Business] and leading to a positive EBITDA of [Confidential detail on EBITDA of Triage Divestment Business]. The Triage Divestment Business is expected to grow at CAGR of [Confidential detail on CAGR of Triage Divestment Business] in the coming years. In order to meet customers' growing demand for POC immunoassay analysers, Triage has [Confidential detail on pipeline products of Triage Divestment Business]. All R&D related to the Triage system takes place at the San Diego facility, which, together with all related pipeline products and plans, forms part of the Triage Divestment business.
- (263) The Triage Divestment Business covers all the assets and personnel of Alere in the market for POC cardiac markers testing for human use. Three products currently manufactured in the San Diego plant are being carved out (Cholestech LDX, visual DOA panels and visual read micro parasite panels). Given the small size of the resources dedicated to the manufacture of these products in the San Diego facility (less than 25%), the viability of the plant is unlikely to be affected. Since the purchaser shall be a player already active in the IVD space, the free capacity generated by the envisaged carved outs may also bring synergies and opportunities for the purchaser.
- (264) On this basis, the Commission considers that the Triage Divestment Businesses as set out in the Final Commitments, constitute viable businesses with well-positioned portfolio products covering the entire value chain, in order to be able to effectively compete on the IVD market for POC cardiac markers on a lasting basis.

5.5.2.3. The BC Commercialization Divestment Business

- (265) In 2015, the commercialization of BNP reagents in BCIS generated [Confidential detail on revenues generated from the BC Commercialization Divestment Business] with a gross margin of [Confidential detail on gross margin of the BC Commercialization Divestment Business] and leading to a positive EBITDA of [Confidential detail on EBITDA of the BC Commercialization Divestment Business]. With [Confidential detail on the BC Commercialization Divestment Business] R&D costs and overall [Confidential detail on the BC Commercialization Divestment Business] operational costs, the BC Commercialization Divestment

Business constitutes a [Confidential detail on the BC Commercialization Divestment Business] business.

- (266) The BC Commercialization Divestment Business covers all the intangible assets as licences, IP rights, pricing and volume history with customers, customer contracts and distribution agreements to continue supplying Danaher customers with the BNP assay for use on Beckman Coulter laboratory analysers.
- (267) On this basis, the Commission considers that the Beckman Divestment Business as set out in the Final Commitments provides viable business.

5.5.3. *Ability of the Final Commitments to be implemented in practice*

- (268) As indicated in Section 5.3.1, respondents to the Commission's market test did not identify any significant risk regarding the implementation of the proposed divestment of the EPOC business. In particular, respondents submitted that the transfer of assets and personnel provided for in the Final Commitments was sufficient to ensure the manufacture and development of the business over time.¹⁴⁹
- (269) As detailed in Section 5.3.2 above, the market test indicated that the Triage Divestment Business and the initially proposed solutions regarding the Beckman Divestment Business created complexity and entanglements between the merged entity and the Purchasers' activities. The Final Commitments have sufficiently addressed these issues.
- (270) Specifically, in relation to the Triage Divestment Business, its scope under the Final Commitments would allow its Purchaser to have control over the full supply chain of the Triage system. In particular, the Purchaser will have control over the full San Diego plant, without a need for plant sharing, leasing and other complex transitional services' agreements that could result in complications and entanglements with the merged entity. In addition, the Purchaser will also have control over the production of the antibody generation, reagent formulation and manufacturing operations guaranteeing access to the key raw materials required for the manufacturing of the Triage system products. Notably, the continued supply of the crucial BNP and Troponin antibodies, including the antibodies used for the BNP reagents for the BCIS form part of the Final Commitments.
- (271) Similarly, the scope of the BC Commercialization Divestment Business is under the Final Commitments clearly separated from the manufacturing of the BNP reagents of the BCIS. As a result, the implementation risks identified during the market test as likely resulting from the need of the purchaser to manufacture own BNP antibodies, no longer arise.
- (272) Moreover, the Final Commitments require that the purchasers of all three Divestment Businesses shall have an established presence in the EEA IVD sector, with a geographic footprint comparable to that of Alere, which, as also emerged from the results of the market test, would ensure their ability to continue effectively

¹⁴⁹ Responses to Questionnaire R2 to Customers of 6 January 2017, question 2 and responses to Questionnaire R1 to Competitors of 6 January 2017, question 13

supplying the EPOC, Triage and BNP reagents for the BCIS products in EEA markets.¹⁵⁰

- (273) Lastly, the closing of the Transaction is conditional upon reaching final agreements for the sale of the Divestment Businesses (so called upfront buyer), which further mitigates any implementation risks.

5.5.4. *Attractiveness of the package for Purchasers*

- (274) Results of our market test show that the EPOC Divestment Business appears attractive, in particular for well-established IVD players with a complementary product portfolio.¹⁵¹ Attractiveness is further evidenced by the fact that a number of potential purchasers would be interested in acquiring it.¹⁵²
- (275) Following the market test results for the Initial Commitments, attractiveness of the Triage and BC Commercialisation Divestment Businesses has been improved in order to address all concerns highlighted by respondents. The Triage and the Beckman Divestment Businesses attracted interests during the market test of the Initial Commitments¹⁵³ and as explained above, they have been improved to remove the identified limitations.
- (276) On this basis, and in particular in view of a number of interested potential purchasers, the Commission considers that the Divestment Businesses are attractive and likely to be acquired by a suitable purchaser.

5.5.5. *Conclusion on Final Commitments*

- (277) For the reasons outlined above, and in view of the results of the market test and the ensuing improvements to the Commitments, the Commission considers the Final Commitments are sufficient to eliminate the serious doubts as to the compatibility of the Transaction with the internal market.

5.6. **Conditions and obligations**

- (278) The commitments in section B of the Annex constitute conditions attached to this decision, as only through full compliance therewith can the structural changes in the relevant markets be achieved. The other commitments set out in the Annex constitute obligations, as they concern the implementing steps, which are necessary to achieve the modifications sought in a manner compatible with the internal market.

¹⁵⁰ Responses to Questionnaire R1 to Competitors of 6 January 2017, questions 14 and 15, 39 and 40, 52 and 53

¹⁵¹ Responses to Questionnaire R1 to Competitors of 6 January 2017, question 19: 38% of respondents consider the EPOC Divestment Business to be attractive against only 13% respondents who consider it to be non-attractive. Most outstanding respondents (50%) have no opinion and bioMérieux explains that "It depends of the purchaser: for a big player, it probably makes sense (market share acquisition) but for a small player, it is difficult to compete with blood gas alone against main players".

¹⁵² Responses to Questionnaire R1 to Competitors of 6 January 2017, question 20

¹⁵³ Responses to Questionnaire R1 to Competitors of 6 January 2017, questions 43 and 44

6. CONCLUSION

- (279) For the above reasons, the Commission has decided not to oppose the notified operation as modified by the commitments and to declare it compatible with the internal market and with the functioning of the EEA Agreement, subject to full compliance with the conditions in section B of the Final Commitments annexed to the present decision and with the obligations contained in the other sections of the said commitments. This decision is adopted in application of Article 6(1)(b) in conjunction with Article 6(2) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission

(signed)
Margrethe VESTAGER
Member of the Commission

Case M.7982 - ABBOTT LABORATORIES / ALERE INC.

IMPROVED COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the “**Merger Regulation**”), Abbott Laboratories (“**Abbott**”) and Alere Inc. (“**Alere**” and, together with Abbott, the “**Parties**”) hereby enter into the following Commitments (the “**Commitments**”) vis-à-vis the European Commission (the “**Commission**”) with a view to rendering Abbott's acquisition of Alere (the “**Concentration**”) compatible with the internal market and the functioning of the EEA Agreement.

This text shall be interpreted in light of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation to declare the Concentration compatible with the internal market and the functioning of the EEA Agreement (the “**Decision**”), in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the “**Remedies Notice**”).

Section A. Definitions

1. For the purpose of the Commitments, the following terms shall have the following meaning:

Abbott: Abbott Laboratories, incorporated under the laws of the state of Illinois, with its headquarters at 100 Abbott Park Road, Abbott Park, Illinois 60064, United States.

Affiliated Undertakings: undertakings controlled by the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the “**Consolidated Jurisdictional Notice**”).

Alere: Alere Inc., a corporation organised and existing under the laws of the state of Delaware, with its principal executive offices at 51 Sawyer Road, Suite 200, Waltham, Massachusetts, United States.

Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as indicated in Section B and described more in detail in the Schedules.

Beckman Agreement: the BNP Assay Development, Manufacture and Supply Agreement dated [...] entered into between [...] (subsequently a wholly-owned subsidiary of Alere, Inc) and Beckman Coulter, Inc., a Delaware corporation having a place of business at 4300 N. Harbor Boulevard, Fullerton, California 92834-3100 (“**Beckman**”), and subsequently acquired by Danaher Corporation, a Delaware corporation having a place of business at 2200 Pennsylvania Avenue, NW, Suite 800W Washington, DC 20037. (“**Danaher**”).

Beckman Analyzers: the automated laboratory instruments that are developed or marketed by or on behalf of Beckman or its Affiliated Undertakings as described in the Beckman Agreement.

Beckman Business: Alere's business of manufacturing and supplying to Danaher the BNP Antibodies used in the manufacture by Danaher of the BNP Assays ("*BC Manufacturing Activities*") and acquiring from Danaher BNP Assays, in each case in accordance with the terms of the Beckman Agreement and commercializing BNP Assays ("*BC Commercialization Divestment Business*").

BNP Antibodies: shall mean the murine monoclonal antibodies binding to the human protein known as B-type natriuretic peptide ("*BNP*").

BNP Assays: the diagnostic B-type natriuretic peptide assay for use in the diagnosis of cardiac diseases in humans developed by Beckman or its Affiliated Undertakings designed for use on the Beckman Analyzers as described in the Beckman Agreement.

Closing: the transfer of the Divestment Business to the Purchaser.

Closing Period: the period of [...] from the Second Effective Date.

Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

Divestment Business: the EPOC Divestment Business, the Triage Divestment Business and the BC Commercialisation Divestment Business

Divestiture Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by Abbott and who has/have received from Abbott the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

EEA: European Economic Area.

EPOC Divestment Business: Alere's business relating to EPOC (Enterprise Point of Care) Blood Analysis System as defined at paragraph 2 of Schedule A.

First Divestiture Period: the period of [...] from the First Effective Date.

First Effective Date: the date of adoption of the Decision.

Hold Separate Manager: the person appointed jointly by, and on terms mutually acceptable to, Abbott and Alere for the Divestment Business to manage the day-to-day business under the supervision of the Monitoring Trustee.

Key Personnel: all personnel necessary to maintain the viability and competitiveness

of the Divestment Business, as listed in the Schedules, including the Hold Separate Manager(s).

Member States: The Member States of the European Economic Area as at the First Effective Date.

Monitoring Trustee: one or more natural or legal person(s) approved by the Commission and appointed by Abbott, and who has/have the duty to monitor the Parties' compliance with the conditions and obligations attached to the Decision.

Parties: Abbott and Alere.

Personnel: all staff currently employed by the Divestment Business, including staff seconded to the Divestment Business, shared personnel as well as the additional personnel listed in the Schedules, including the Hold Separate Manager.

Purchaser: the entity or entities approved by the Commission to acquire each Divestment Business in accordance with the criteria set out in Section D.

Purchaser Criteria: the criteria laid down in paragraph 18 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

Second Effective Date: [...].

Schedule: the schedules to these Commitments describing more in detail the Divestment Business. The schedules to these Commitments form an integral part of the Commitments.

Triage Divestment Business: Alere's businesses relating to its Triage System as defined in Schedule B.

Triage: Triage System as defined at paragraph 2 of Schedule B.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee, if appointed, as the case may be.

Trustee Divestiture Period: the period of [...] from the end of the First Divestiture Period.

Section B. The commitment to divest and the Divestment Business

Commitment to divest

2. In order to maintain effective competition, Abbott commits to divest, or procure the divestiture of, the Divestment Business by the end of the Closing Period as a going concern to one or more purchasers fulfilling the criteria set out in Section D and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 19 of these Commitments. To carry out the divestiture, Abbott commits to find one or more purchasers and to enter into a final binding sale and purchase agreement with each purchaser for the sale of the Divestment Business within

the First Divestiture Period, including any extensions thereto. If Alere and Abbott have not entered into such an agreement at the end of the First Divestiture Period, Alere and Abbott shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 33 in the Trustee Divestiture Period.

3. The Concentration shall not be implemented before Alere and Abbott, or the Divestiture Trustee, as the case may be, has entered into final binding sale and purchase agreement(s) for the sale of the Divestment Business with the purchaser(s), and the Commission has approved the purchaser(s) and the terms of sale in accordance with paragraph 19.
4. Abbott shall be deemed to have complied with this commitment if:
 - a) by the end of the Trustee Divestiture Period, Abbott, Alere or the Divestiture Trustee has entered into final binding sale and purchase agreement(s) and the Commission approves the proposed purchaser(s) and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 19;
 - b) the Closing of the sale of the Divestment Business to the Purchaser takes place within the Closing Period;
 - c) all other obligations in the Commitments and its Schedules have been complied with, including those related to transitional support and supply.
5. In order to maintain the structural effect of the Commitments, Abbott shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Business, unless, following the submission of a reasoned request from Abbott showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 47 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.

Structure and definition of the Divestment Business

6. The Divestment Business consists of the EPOC Divestment Business, the Triage Divestment Business and the BC Commercialization Divestment Business. The legal and functional structure of the Divestment Business as operated to date, described in more detail in Schedules A, Schedule B and Schedule C, include all assets and staff that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business, in particular:
 - a) all tangible and intangible assets (including intellectual property rights) of the Divestment Business;
 - b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business;

- c) all contracts, leases, commitments and customer orders of the Divestment Business;
 - d) all customer, credit and other records of the Divestment Business; and
 - e) the Personnel (except as otherwise agreed with the Purchaser).
7. In addition, the Divestment Business includes the benefit, for a transitional period of up to [...] after Closing and on terms and conditions equivalent to those at present afforded to the Divestment Business, of all current arrangements under which Alere or its Affiliated Undertakings supply products or services to the Divestment Business, as detailed in Schedule A, Schedule B and Schedule C, unless otherwise agreed with the Purchaser. Strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from such supply arrangements (for example, product roadmaps) will not be shared with, or passed on to, anyone outside the Divestment Business operations.

Section C. Related commitments

Preservation of viability, marketability and competitiveness

8. From the First Effective Date until the Second Effective Date, Alere shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. From the Second Effective Date until Closing, Abbott shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. In particular Abbott and Alere each undertake during the relevant periods:
- a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;
 - b) to make available, or procure to make available, sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans;
 - c) to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage all Key Personnel to remain with the Divestment Business, and not to solicit or move any Personnel to the remaining businesses of the Parties. Where, nevertheless, individual members of the Key Personnel exceptionally leave the Divestment Business, Abbott or Alere as the case may be shall provide a reasoned proposal to replace the person or persons concerned to the Commission and the Monitoring Trustee. Abbott or Alere as the case may be must be able to demonstrate to the Commission that the replacement is well

suited to carry out the functions exercised by those individual members of the Key Personnel. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission.

Hold-separate obligations

9. Alere commits, from the First Effective Date until the Second Effective Date, to keep the Divestment Business separate from the businesses that Alere will be retaining and to ensure that unless explicitly permitted under these Commitments: (i) management and staff of the businesses retained by Alere have no involvement in the Divestment Business; (ii) the Key Personnel and Personnel of the Divestment Business have no involvement in any business retained by Alere and do not report to any individual outside the Divestment Business.
10. Abbott commits, from the Second Effective Date until Closing, to keep the Divestment Business separate from the businesses that Abbott will be retaining and to ensure that unless explicitly permitted under these Commitments: (i) management and staff of the businesses retained by Abbott have no involvement in the Divestment Business; and (ii) the Key Personnel and Personnel of the Divestment Business have no involvement in any business retained by Abbott and do not report to any individual outside the Divestment Business.
11. From the First Effective Date until the Second Effective Date, and from the Second Effective Date until Closing, each of Alere and Abbott respectively shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable entity separate from the businesses which the Parties are retaining. Immediately after the First Effective Date, Abbott and Alere shall jointly appoint a Hold Separate Manager on terms mutually acceptable to Abbott and Alere. The Hold Separate Manager, who shall be part of the Key Personnel, shall manage the Divestment Business independently and in the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by the Parties. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to the procedure laid down in paragraph 8(c) of these Commitments. The Commission may, after having heard Abbott and Alere, require Abbott and Alere (or, as the case may be, after the Second Effective Date, Abbott) to replace the Hold Separate Manager.
12. To ensure that the Divestment Business is held and managed as a separate entity the Monitoring Trustee shall exercise respectively Alere or Abbott's rights as the case may be as a shareholder in the legal entity that constitutes the Divestment Business (except for its rights in respect of dividends that are due before Closing), with the aim of acting in the best interest of the business, which shall be determined on a stand-alone basis, as an independent financial investor, and with a view to fulfilling the Parties' obligations under the Commitments. Furthermore, the Monitoring Trustee shall have the power to replace members of the supervisory board or non-executive directors of the board of directors, who have been appointed on behalf of Alere or Abbott as the case may be. Upon request of the Monitoring Trustee, Alere or Abbott as the case may be shall resign as a member of the boards or shall cause such members of the boards to resign.

Ring-fencing

13. Alere shall implement, or procure to implement, all necessary measures to ensure that it does not, after the First Effective Date, obtain any Confidential Information relating to the Divestment Business and that any such Confidential Information obtained by the Alere before the First Effective Date will be eliminated and not be used by the Parties. Abbott shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Second Effective Date, obtain any Confidential Information relating to the Divestment Business and that any such Confidential Information obtained by Abbott will be eliminated and not be used by the Parties. In particular, the participation of the Divestment Business in any central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Business. The Parties may obtain or keep information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or the disclosure of which to the Parties are required by law.

Non-solicitation clause

14. The Parties undertake, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Key Personnel transferred with the Divestment Business for a period of two (2) years after Closing.

Due diligence

15. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, Abbott and Alere shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:
 - a) provide to potential purchasers sufficient information as regards the Divestment Business;
 - b) provide to potential purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel.

Reporting

16. Abbott shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the First Effective Date (or otherwise at the Commission's request). Abbott shall submit a list of all potential purchasers having expressed interest in acquiring the Divestment Business to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential purchasers within five days of their receipt.
17. Abbott shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

18. In order to be approved by the Commission, each Purchaser must fulfil the following criteria:
- a) The Purchaser shall be independent of and unconnected to the Parties and their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture);
 - b) The Purchaser shall have an established presence, including distribution and sales capabilities, in the In Vitro Diagnostics (IVD) sector in the EEA with [...];
 - c) The Purchaser shall have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors;
 - d) The acquisition of the Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business. In addition, the Purchaser must show to the Commission satisfactory evidence that it has obtained the consents of [...] and any other critical intellectual property rights holders for the transfer of the relevant licenses and/or use of the relevant other IP rights.
19. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Business shall be conditional on the Commission's approval. When Abbott has reached an agreement (or agreements) with the purchaser (or purchasers) of the EPOC Divestment Business, Triage Divestment Business and BC Commercialization Divestment Business, it shall submit a fully documented and reasoned proposal (s), including a copy of all the final agreement(s), within one week to the Commission and the Monitoring Trustee. In case Abbott does not propose to divest the Divestment Businesses to the same purchaser, the Commission will take the decision approving the proposed purchasers only after having assessed the complete information related to the proposed buyers of the EPOC Divestment Business, the Triage Divestment Business and the BC Commercialization Divestment Business, and all agreements concluded in relation to those divestments.
20. Abbott must be able to demonstrate to the Commission that each purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commission's Decision and the Commitments. For the approval, the Commission shall verify that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. At the request of Abbott, the Commission may approve the sale of the Divestment Business without one or more Assets or parts of the Personnel, or by substituting one

or more Assets or parts of the Personnel with one or more different assets or different personnel, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

Section E. Trustee

I. Appointment procedure

21. Abbott shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. Abbott commits not to close the Concentration before the appointment of a Monitoring Trustee.
22. If Abbott has not entered into a binding sale and purchase agreement regarding the Divestment Business one month before the end of the First Divestiture Period or if the Commission has rejected a Purchaser proposed by Abbott at that time or thereafter, Abbott shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.
23. The Trustee shall:
 - i. at the time of appointment, be independent of Abbott and its Affiliated Undertakings;
 - ii. possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and
 - iii. neither have nor become exposed to a Conflict of Interest.
24. The Monitoring Trustee and the Divestiture Trustee shall be remunerated by Abbott in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by Abbott

25. No later than two (2) weeks after the First Effective Date, Abbott shall submit to the Commission for approval the name or names of one or more natural or legal persons whom Abbott proposes to appoint as the Monitoring Trustee.
26. In the event that Abbott has not entered into a binding sale and purchase agreement regarding the Divestment Business one month before the end of the First Divestiture Period, or otherwise on request by the Commission, Abbott shall submit a list of one or more persons whom Abbott proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 23 and shall include:

- a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;
- b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks;
- c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or rejection by the Commission

27. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, Abbott shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, Abbott shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by Abbott

28. If all the proposed Trustees are rejected, Abbott shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 21 and 27 of these Commitments.

Trustee nominated by the Commission

29. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Abbott shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

30. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or Abbott, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

31. Monitoring Trustee shall:
 - i. propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.
 - ii. oversee, in close co-operation with the Hold Separate Manager, the on-going

management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by the Parties with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

- a) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by the Parties, in accordance with paragraphs 8 and 9 of these Commitments;
 - b) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 11 of these Commitments;
 - c) supervise all transitional agreements in relation to the sale of the EPOC Divestment Business, Triage Divestment Business and BC Commercialization Divestment Business;
 - d) with respect to Confidential Information:
 - determine all necessary measures to ensure that Alere does not after the First Effective Date obtain any Confidential Information relating to the Divestment Business except as provided in paragraph 13 of these Commitments,
 - in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,
 - make sure that any Confidential Information relating to the Divestment Business obtained by the Parties before the Effective Date is eliminated and will not be used by the Parties except as provided in paragraph 13 of these Commitments, and
 - decide whether such information may be disclosed to or kept by the Parties as the disclosure is reasonably necessary to allow the Parties to carry out the divestiture or as the disclosure is required by law;
 - e) monitor the splitting of assets, including in transferring or assigning the intellectual property and know-how, and the allocation of Personnel between the Divestment Business and Abbott, Alere or Affiliated Undertakings;
- iii. propose to the Parties such measures as the Monitoring Trustee considers necessary to ensure their compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, the

holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;

- iv. review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process:
 - a) potential purchasers receive sufficient and correct information relating to the Divestment Business and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and
 - b) potential purchasers are granted reasonable access to the Personnel;
 - v. act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;
 - vi. provide to the Commission, sending Abbott and Alere a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets and the allocation of Personnel so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;
 - vii. promptly report in writing to the Commission, sending Abbott and Alere a non- confidential copy at the same time, if it concludes on reasonable grounds that the Parties are failing to comply with these Commitments;
 - viii. within one week after receipt of the documented proposal referred to in paragraph 19 of these Commitments, submit to the Commission, sending Abbott and Alere a non- confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of the Divestment Business without one or more Assets or not all of the Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser;
 - ix. assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.
32. If the Monitoring and Divestiture Trustee are not the same legal or natural persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and obligations of the Divestiture Trustee

33. If appointed, the Divestiture Trustee shall sell at no minimum price the Divestment Business to one or more Purchasers, provided that the Commission has approved both the Purchaser and the final binding sale and purchase agreement(s) (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 18 and 19 of these Commitments. The Divestiture Trustee, if appointed, shall include in the sale and purchase agreement (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in such sale and purchase agreement(s) such customary representations and warranties and indemnities as are reasonably required to effect the sale. If appointed, the Divestiture Trustee shall protect the legitimate financial interests of Abbott, subject to Abbott's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.
34. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to Abbott.

III. Duties and obligations of the Parties

35. The Parties shall provide and shall cause its advisors to provide the Trustee with all such co-operation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of the Parties' or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and Abbott, Alere and the Divestment Business shall provide the Trustee upon request with copies of any document. Abbott, Alere and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.
36. The Parties shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. The Parties shall:
 - a) provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure; and
 - b) inform the Monitoring Trustee on possible purchasers, submit lists of potential purchasers at each stage of the selection process, including the offers made by potential purchasers at those stages, and keep the Monitoring Trustee informed

of all developments in the divestiture process.

37. Abbott and Alere shall grant or procure its Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, Abbott and Alere shall cause the documents required for effecting the sale and the Closing to be duly executed.
38. Abbott and Alere (severally but not jointly) shall indemnify the Trustee and its employees and agents (each an “*Indemnified Party*”) and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to Abbott or Alere for, any liabilities arising out of the performance of the Trustee’s duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.
39. At the expense of Abbott, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Abbott’s approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should Abbott refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Abbott. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 38 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Abbott during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.
40. The Parties agree that the Commission may share Confidential Information proprietary to each of Abbott or Alere with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17 (1) and (2) of the Merger Regulation apply *mutatis mutandis*.
41. Abbott agrees that the contact details of the Monitoring Trustee are published on the website of the Commission’s Directorate-General for Competition and they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.
42. For a period of 10 years from the First Effective Date the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, discharge and reappointment of the Trustee

43. If the Monitoring Trustee or any Divestiture Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

- a) the Commission may, after hearing the Trustee and Abbott, require Abbott to replace the Trustee; or
 - b) Abbott may, with the prior approval of the Commission, replace the Trustee.
44. If the Monitoring Trustee or any Divestiture Trustee is removed according to paragraph 43 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 21-29 of these Commitments.
45. Unless removed according to paragraph 43 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The review clause

46. The Commission may extend the time periods foreseen in the Commitments in response to a request from Abbott or, in appropriate cases, on its own initiative. Where Abbott requests an extension of a time period, it shall submit a reasoned request to the Commission no later than [...] before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to Abbott. Only in exceptional circumstances shall Abbott be entitled to request an extension within the [...] of any period.
47. The Commission may further, in response to a reasoned request from Abbott showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to Abbott. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

Section G. Entry into force

48. The Commitments shall take effect upon the date of adoption of the Decision.

SCHEDULE A

EPOC DIVESTMENT BUSINESS

1. The EPOC Divestment Business, as operated to date, has the following legal and functional structure:

Alere's global EPOC business includes two leased buildings in Ottawa, Canada, occupied and operated by Epocal Inc., a company organized under the laws of Canada and a wholly owned subsidiary of Alere Inc ("*Epocal*"). Its registered office is at 2060 Walkley Road Ottawa, ON K1G 3P5 Canada.

2. The EPOC Divestment Business consists of the EPOC (Enterprise Point of Care) Blood Analysis System ("EPOC System") which includes the global manufacturing, development and commercialization of:
 - a) the EPOC BGEM Test Card for human and for veterinary use, including all related pipeline products;
 - b) the EPOC Reader for human and for veterinary use, including all related pipeline products;
 - c) the EPOC Host 2 Mobile Computer for human and for veterinary use, including all related pipeline products.

The marketed and pipeline products listed above comprise all analyzers and reagents/tests sold (or in development) belonging to the EPOC System.

3. The EPOC Divestment Business includes, but is not limited to:

The following main tangible assets used for the production and development of the EPOC System, in particular the EPOC manufacturing and R&D facility and equipment, including:

- i. Production room and room controls (HVAC);
- ii. R&D and lab equipment;
- iii. Computers/ office equipment;
- iv. Inventories (raw material inventory, WIP, EPOC specific);
 - a) The following table lists the tangible production assets:

Table 1: Main tangible production assets of the EPOC Divestment business

Tangible assets	Quantity	Value (CAD \$)
Dedicated EPOC equipment		
EPOC assembly lines and equipment	[...]	[...]
Spare parts for equipment and assembly lines	[...]	[...]
Machinery and equipment specific to EPOC	[...]	[...]
Main tangible assets		
Production room and room controls (HVAC)	[...]	[...]
R&D and lab equipment	[...]	[...]
Computers/ equipment	[...]	[...]
Inventories (raw material inventory, WIP, EPOC specific)	[...]	[...]
Total	[...]	[...]

a) the following main intangible assets:¹

- i. all patents owned by Alere that are solely or predominantly used for the EPOC System, including the ones owned by Epocal listed in Table 2 below;
- ii. perpetual, irrevocable, assignable, sub-licensable royalty free licenses will be granted to the Purchaser for any patents related to the EPOC System but which are not solely or predominantly used for the EPOC System;
- iii. licenses and rights in intellectual property arising under contracts to which Alere is a party for the manufacture and development of the EPOC System (subject to obtaining all relevant third party consents, recognizing that the Parties will use their reasonable best efforts to obtain such consents and it being understood that, pursuant to Section D, third parties' consent of critical intellectual property rights holders for the transfer of the relevant licenses and/or use of the relevant other IP rights is a pre-condition for the approval of the purchaser);

¹ Subject to a license back from the Purchaser in respect of any such intangible assets for the purposes of maintaining the retained businesses or products of Alere.

Table 2: List of the US patents held in relation to the EPOC system²

Alere Reference Number	U.S. Patent/Application No.	US Expiration Date
EPOC002	US6,896,778	4 June 2021
EPOC002	US7,824,529	4 June 2021
EPOC006	US7,094,330	15 May 2024
EPOC007	US8,506,778	25 June 2023
EPOC007	US7,842,234	14 August 2026
EPOC008	US7,767,068	18 February 2026
EPOC010	US6,845,327	26 November 2022

- iv. all necessary trademarks relating to the EPOC Divestment Business, except "*Alere*" for which a license and/or right to use the trademark will be granted for as long as needed to avoid supply disruption to the divestment business;
 - v. all trade secrets, confidential know-how, confidential customer data, or other confidential information and certain other intellectual property used exclusively or predominantly in the EPOC Divestment Business;
 - vi. co-ownership of an undivided interest (with Alere and its Affiliated Undertakings) in trade secrets, confidential know-how, confidential customer data, or other confidential information and other intellectual property used both in the EPOC Divestment Business and in other businesses of Alere and its Affiliated Undertakings, to the extent used in the EPOC Divestment Business;
- b) to the extent they can transfer by law all necessary regulatory clearances and authorizations;
 - c) all customer contracts, lists, information and history;
 - d) all inventories, including raw materials, works in process, semi-finished and finished products, stores, replacement and spare parts, packaging and labelling materials, operating supplies and inventory on consignment, in transit or deposited in a warehouse, in each case to the extent used in the EPOC Divestment Business,
 - e) all advertising, marketing, training and promotional materials, books, records,

² The corresponding non-US patents held by Alere in other jurisdictions are the main non-US patents in relation to EPOC.

files, tax records, customers lists and history used exclusively or predominantly in the EPOC Divestment Business, and co-ownership of an undivided interest of all other books, records, files, tax records, customers lists and history to the extent related to the EPOC Divestment Business;

- f) all of the following contracts to the extent related to EPOC (subject to obtaining all relevant third party consents, recognizing that the Parties will use their reasonable best efforts to obtain such consents):
 - i. all supply contracts (including the ones listed in **Annex RM A5**);
 - ii. the building lease contract in relation to:
 - A. the Walkley facility with a total of [...] square feet (see **Annex RM A3**);
 - B. the Brookfield facility with a total of [...] square feet (see **Annex RM A2**);
 - iii. all third party distribution contracts (including the ones listed in **Annex RM A6**);
 - iv. all manufacturing, packaging and R&D agreements; and
 - v. all other relevant contracts for the viability of the EPOC Divestment Business.
- g) Personnel necessary for the continued viability and competitiveness of the EPOC Divestment Business, including, but not necessarily limited to, the personnel listed in Table 3 below:

Table 3: EPOC dedicated personnel

Function	Number
Business intelligence	[...]
Operations chemical prep, operators, technicians and managers	[...]
Manufacturing engineering and technicians	[...]
Human resources	[...]
Lean program, mfg. lean activities	[...]
Operators, managers and support team	[...]
Process engineering, validations	[...]
Quality	[...]
Research and Design	[...]
Systems, readers, hosts and cap tube production	[...]
Finished goods testing and product release	[...]
[...]	[...]
[...]	[...]
[...]	[...]
[...]	[...]
Total	[...]

- h) transfer of any pipeline products (including the ones listed in the Form RM) predominantly relating to the EPOC System, and right to access other pipeline products which are intended to be used in relation to EPOC System if any.
4. If there are Personnel providing customer services, distribution or sales and marketing services for the EPOC Divestment Business that are not covered by paragraph 3 of this Schedule but which are both used in the EPOC Divestment Business and necessary for the continued viability and competitiveness of the EPOC Divestment Business, Purchaser will have the opportunity to extend an offer of employment to such Personnel.
 5. To the extent that any regulatory clearance is required by the Purchaser in respect of the transfer of any existing or pipeline product of the EPOC Divestment Business, Abbott and Alere will use their reasonable best efforts to assist the Purchaser to obtain any such clearances.

6. If there is any asset or personnel which is not covered by this Schedule A but which is both used (exclusively or not) in the EPOC Divestment Business and necessary for the continued viability and competitiveness of the EPOC Divestment Business, that asset or personnel, or adequate substitute will be offered to the potential purchasers.

SCHEDULE B

TRIAGE DIVESTMENT BUSINESS

1. The Triage Divestment Business, as operated to date, has the following legal and functional structure:

Alere's global Triage Divestment Business is primarily conducted at a facility in San Diego, California, that is occupied and operated by Alere [...], a company organized under the laws of the the State of [...]and a subsidiary of Alere Inc. (the "*San Diego facility*"). All of the San Diego facility will be included in the Triage Divestment Business.

2. The Triage Divestment Business consists of the Triage System at global level and more specifically the manufacturing, development and commercialization of:

- a) the Triage MeterPro System analyser including all related pipeline products;

- b) the Triage System tests (including all related pipeline products) as follows:

- i. Triage B-type Natriuretic peptide (BNP);
- ii. Triage NT-Pro-BNP;
- iii. Triage Troponin I;
- iv. Triage Cardiac Panel (CK-MB, Myoglobin, and TnI);
- v. Triage Cardio3 Panel (CK-MB, TnI, BNP);
- vi. Triage Cardio2 Panel (TnI, BNP);
- vii. Triage Profiler SOB Panel (Myoglobin, CK-MB, TnI, BNP, D-Dimer);
- viii. Triage Cardiorenal Panel (NGAL, BNP) (which is not commercialized currently);
- ix. Triage PLGF (which is not commercialized currently); and
- x. Triage TOX Drug Screen.

The marketed and pipeline products listed above comprise all analyzers and reagents/tests sold (or in development) belonging to the Triage System.

3. The Triage Divestment Business also includes the manufacturing and supplying to Danaher the BNP Antibodies used in the manufacture by Danaher of the BNP Assays, the BC Manufacturing Activities.
4. Since the Triage Divestment Business includes the antibody generation and reagent formulation and manufacturing equipment and personnel at the San Diego site, which

support other Alere products unrelated to Triage and to the BC Manufacturing Activities or BC Commercialization Divestment Business ("**non-Triage/non-BC Products**"), a transitional supply agreement to supply Alere with reagents (and any raw materials, as necessary) for non-Triage/non-BC Products will be made available by the Purchaser to Alere for a period of no more than three years from Closing, unless extended by Abbott and Purchaser with the consent of the Monitoring Trustee.

5. For the sake of completeness, however, the Triage Divestment Business will not include:
 - a) any intangible assets (whether owned by Alere or in-licensed from third parties) exclusively related to non-Triage/non-BC Products;
 - b) any supply agreements between third party suppliers and Alere which concern exclusively the supply of raw materials for non-Triage/non-BC Products;
 - c) any customer contracts between third party customers and Alere which concern exclusively the supply of non-Triage/non-BC Products by Alere;
 - d) the transfer of the personnel, tangible and intangible assets exclusively dedicated to the manufacture and commercialization of the Alere Cholestech LDX Analyzer, visual read DOA panels and the visual read micro parasite panels (none of which are used or intended to be used with the Triage System).

6. The Triage Divestment Business includes, but is not limited to:
 - a) the tangible assets used for the production and development of Triage and in the BC Manufacturing Activities, in particular the Triage manufacturing and R&D facility and equipment used exclusively or predominantly for Triage or the BC Manufacturing Activities.
 - i. the map in Schedule B shows the plant layout for the San Diego facility (comprising four buildings) with a total of [...] sq. ft. (~[...] square metres) of manufacturing, R&D, administrative and related space. Purchaser will own the San Diego facility and the land on which it is located. The retained Alere activities will be transferred out of the San Diego facility.
 - ii. the following table lists the Triage Divestment Business's tangible production assets – facilities, equipment and inventories:

Table 4: Tangible production assets of the San Diego facility

Tangible assets	Quantity	Value (US \$)
Dedicated Triage equipment		
Triage automation	[...]	[...]
Triage manual lines	[...]	[...]
Front and back end assembly equipment	[...]	[...]
Main tangible assets		
Other Triage machinery, improvements and tooling	[...]	[...]
Lab equipment and improvements	[...]	[...]
R&D equipment and improvements ¹	[...]	[...]
Inventories- raw material, WIP, pre-paid, inspection (Net)	[...]	[...]
Buildings		
ASD Buildings (as of 1 January 2016)	[...]	[...]
ASD Plant land	[...]	[...]
Total	[...]	[...]

iii. for the avoidance of doubts, tangible assets include cell lines and calibration materials used for the manufacturing of the BNP Antibodies.

b) the following main intangible assets:²

- i. all patents exclusively or predominantly relating to the Triage Divestment Business.;
- ii. a non-exclusive perpetual, irrevocable, sub-licensable, royalty free license under other patents owned by Alere to the extent such patents include a claim that is practiced by Triage Divestment Business;
- iii. full assignment of all relevant licenses and rights used exclusively or predominantly in the Triage Divestment Business (subject to obtaining all

¹ For the sake of completeness, this valuation does not include certain discrete assets related to R&D antibody discovery activities at the San Diego facility that are included in the scope of the Triage Divestment Business.

² Subject to a license back from the Purchaser in respect of any such intangible assets for the purposes of maintaining the retained businesses or products of Alere.

- relevant third party consents, recognizing that the Parties will use their reasonable best efforts to obtain such consents and it being understood that, pursuant to Section D, third parties' consent of critical intellectual property rights holders for the transfer of the relevant licenses and/or use of the relevant other IP rights is a pre-condition for the approval of the purchaser);
- iv. assignment of, or other non-exclusive, irrevocable, sub-licensable, royalty free right or license to or under, any other relevant licenses to the extent related to the Triage Divestment Business (subject to obtaining all relevant third party consents, recognizing that the Parties will use their reasonable best efforts to obtain such consents and it being understood that, pursuant to Section D, third parties' consent of critical intellectual property rights holders for the transfer of the relevant licenses and/or use of the relevant other IP rights is a pre-condition for the approval of the purchaser);
 - v. all rights held by Alere under the [...] license for the manufacturing, development and commercialization of Triage products and for the BC Manufacturing Activities (subject to obtaining relevant third party consents, recognizing that the Parties will use their reasonable best efforts to obtain such consents and it being understood that, pursuant to Section D, [...]s consent for the transfer of the relevant licenses and/or use of the relevant other IP rights is a pre-condition for the approval of the purchaser);
 - vi. all trademarks relating to the Triage Divestment Business, except "Alere" for which a license and/or right to use the trademark will be granted for a reasonable term to avoid supply disruption to the Divestment Business;
 - vii. all trade secrets, confidential know-how, confidential customer data, or other confidential information and certain other intellectual property used exclusively or predominantly in the Triage Divestment Business;
 - viii. co-ownership of an undivided interest (with Alere and its Affiliated Undertakings) in trade secrets, confidential know-how, confidential customer data, or other confidential information and other certain intellectual property used both in the Triage Divestment Business and in other businesses of Alere and its Affiliated Undertakings, to the extent used in the Triage Divestment Business;
- c) to the extent they can transfer by law, all necessary regulatory clearances and authorizations used exclusively or predominantly in the distribution, marketing, promotion, selling or offering for sale of the Triage System;
 - d) all inventories, including raw materials, works in process, semi-finished and finished products, stores, replacement and spare parts, packaging and labelling materials, operating supplies and inventory on consignment, in transit or deposited in a warehouse, in each case to the extent used in the Triage Divestment Business;

- e) all advertising, marketing, training and promotional materials, books, records, files, tax records, customers lists, information and history used exclusively in the Triage Divestment Business, and co-ownership of an undivided interest of all other books, records, files, tax records, customers lists, information and history to the extent related to the Triage Divestment Business;
- f) all of the following contracts to the extent related to Triage Divestment Business (subject to obtaining all relevant third party consents, recognizing that the Parties will use their reasonable best efforts to obtain such consents):
 - i. all supply contracts (including the ones listed in **Annex RMB4**);
 - ii. all distribution agreements (including the ones listed in **Annex RMB5**);
 - iii. all manufacturing agreements, including the third party manufacturing agreement with [...];
 - iv. all packaging agreements, including the third party packaging contract with [...];
 - v. all independent contractor contracts, excluding any agreements used in the Triage Divestment Business that relate to the division, corporate office, overhead or back-office functions of Alere or its Affiliated Undertakings;
 - vi. Customer contracts, including the Beckman Agreement (or a novation thereof) to the extent it relates to the supply of BNP Antibodies.
- g) Personnel necessary for the continued viability and competitiveness of the Triage Divestment Business including, but not necessarily limited to, the personnel listed in Table 5 below:

Table 5: Triage Divestment Business dedicated personnel

Function	Number
QA/RA	[...]
Technical services	[...]
R&D	[...]
Operations	[...]
G&A	[...]
Census (Software)	[...]
Marketing	[...]
Total	[...]

Table 6: List of employees indispensable for the operation of the Triage Divestment Business

Business area	Name	Function
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]
[...]	[...]	[...]

h) transfer of all pipeline products predominantly related to the Triage Divestment Business including the products listed below, and right to access other pipeline products which are intended to be used in relation to the Triage Divestment Business if any:

[...].

7. If there are Personnel providing customer services, distribution or sales and marketing services for the Triage Divestment Business that are not covered by paragraph 6 of this Schedule but which are both used in the Triage Divestment Business and necessary for the continued viability and competitiveness of the Triage Divestment Business, Purchaser will have the opportunity to extend an offer of employment to such Personnel.
8. To the extent that any regulatory clearance is required by the Purchaser in respect of the transfer of any existing or pipeline product of the Triage Divestment Business, Abbott and Alere will use their reasonable best efforts to assist the Purchaser to obtain any such clearances.
9. If there is any asset or personnel which is not covered by this Schedule B but which is both used (exclusively or not) in the Triage Divestment Business and necessary for the continued viability and competitiveness of the Triage Divestment Business, that asset, or personnel, or adequate substitute will be offered to the potential purchasers.

SCHEDULE C

BC COMMERCIALIZATION DIVESTMENT BUSINESS

1. The BC Commercialization Divestment Business is part of the Beckman Business, as defined in Section A of these Commitments.
2. The BC Commercialization Divestment Business consists of the commercialization of BNP Assays to customers of Danaher for use on the Beckman Analyzers, and also includes the personnel required for such commercialization.
3. The BC Commercialization Divestment Business shall not, however, include the antibody generation and reagent formulation and manufacturing operations at the San Diego site, which support Triage, BC Manufacturing Activities and many non-Triage/non-BC Products.
4. The BC Commercialization Divestment Business includes, but is not limited to:
 - a) the following main intangible assets:
 - i. licenses and rights in intellectual property arising under contracts to which Alere is a party for commercializing BNP Assays (subject to obtaining all relevant third party consents, recognizing that the Parties will use their reasonable best efforts to obtain such consents and it being understood that, pursuant to Section D, third parties' consent of critical intellectual property rights holders for the transfer of the relevant licenses and/or use of the relevant other IP rights is a pre-condition for the approval of the purchaser) ;
 - ii. all rights held by Alere under the [...] license for the commercialization of BNP Assays (subject to obtaining relevant third party consents, recognizing that the Parties will use their reasonable best efforts to obtain such consents and it being understood that, pursuant to Section D, [...]s consent for the transfer of the relevant licenses and/or use of the relevant other IP rights is a pre-condition for the approval of the purchaser);
 - iii. all trademarks relating to the BC Commercialization Business, except "Alere" or any trademark relating to the Triage Divestment Business. For "Alere" and other trademarks relating to both the Triage Divestment Business and the BC Commercialization Divestment Business, a license and right to use the trademarks will be granted for a reasonable term to avoid supply disruption;
 - iv. all trade secrets, confidential know-how, confidential customer data, or other confidential information and other intellectual property used exclusively or predominantly in the BC Commercialization Divestment Business which shall include, without limitation:
 - A. supporting documentation, including marketing and customer service procedures;

B. pricing and volume history with customers,

- v. co-ownership of an undivided interest (with Alere and its Affiliated Undertakings and their respective successors and assigns) in the trade secrets, confidential know-how, confidential customer data, or other confidential information and certain other intellectual property used both in the BC Commercialization Divestment Business (but not predominantly) and in other businesses of Alere and its Affiliated Undertakings, to the extent used in the BC Commercialization Divestment Business;
 - b) to the extent they can transfer by law, all necessary regulatory clearances, registrations and authorizations used exclusively or predominantly in the distribution, marketing, promotion, selling or offering for sale of the BNP Assays, and a reasonable best efforts obligation to provide all reasonable assistance in obtaining replacement regulatory clearances, registrations and authorizations where appropriate;
 - c) all inventories, including raw materials, works in process, semi-finished and finished products, stores, replacement and spare parts, packaging and labelling materials, operating supplies and inventory on consignment, in transit or deposited in a warehouse, in each case to the extent used in the BC Commercialization Divestment Business, and other than those used in the BC Manufacturing Activities;
 - d) all advertising, marketing, training and promotional materials, books, records, files, tax records, customers lists, information and history used exclusively in the BC Commercialization Divestment Business, and co-ownership of an undivided interest of all other books, records, files, tax records, customers lists, information and history to the extent related to the BC Commercialization Divestment Business;
 - e) all of the following contracts to the extent related to the BC Commercialization Divestment Business (subject to obtaining all relevant third party consents, recognizing that the Parties will use their reasonable best efforts to obtain such consents):
 - i. all supply contracts, including the Beckman Agreement (or a novation thereof) to the extent it relates to the supply of BNP Assays;
 - ii. all distribution agreements; and
 - iii. customer contracts.
 - f) At the option of the Purchaser, personnel providing customer services, distribution or sales and marketing services for the BC Commercialization Divestment Business.
5. If there is any asset or personnel which is not covered by this Schedule C but which

is both used (exclusively or not) in the BC Commercialization Divestment Business and necessary for the continued viability and competitiveness of the BC Commercialization Business, that asset, or personnel, or adequate substitute will be offered to the potential purchasers.

SCHEDULE B – TABLE OF ANNEXES

No	Title
1.	Annex Schedule B: Map of the San Diego facility

ANNEX SCHEDULE B: ASD PLANT LAYOUT

[...]