Annex 3: Search on validation studies

As of 06 April 2020, no information of concluded validation studies could be retrieved from public online resources.

The global non-profit organisation FIND (https://www.finddx.org/) is conducting in partnership with the WHO independent evaluations of nucleic acid tests and immunoassays. A call for expression of interest (EOI) for test developers of *in vitro* diagnostics (IVDs) that detect SARS-CoV-2 nucleic acid (molecular tests) has been launched on 19 February 2020 (https://www.finddx.org/covid-19/sarscov2-eval-molecular/). A parallel call has been launched on 13 March 2020 for test developers of immunoassays (https://www.finddx.org/covid-19/sarscov2-eval-immuno/).

Applications received have been selected according to scoring criteria (including for molecular tests: declared limit of detection, regulatory status of the assay, type of organisation and implemented quality management; for immunoassays: regulatory status of the assay and time to market, production and distribution capacity and clinical and analytical performance).

For immunoassays priority was given to rapid diagnostic tests (RDT). Five antigen detection RDT and 53 antibody detection RTD have been included in the first round evaluation.

The evaluation of both molecular tests and immunoassays is still ongoing and performance data are not yet available. The list of molecular tests and immunoassays selected is available from the FIND webpage. No recommendation can be given until the expert assessments are finalised and the data are made available.

In line with research gaps and priorities identified by the WHO Forum and due to the recognised urgency in having reliable tests to respond to the COVID-19 emergency, parallel efforts are toward confirmation of diagnostic relevance of available methods and devices. The additional independent assessments, planned or ongoing, that could be retrieved as of 6 April 2020 from online resources are listed below:

CareAccess Research (https://www.careaccessresearch.com/) has announced a validation trial in the US in conjunction with the FDA. The validation trial will focus on rapid self-tests developed by a private company for at-home use. No further information could be retrieved.

Mologic, a UK company experienced in Ebola, has initiated an independent assessment and validation of COVID-19 diagnostic tests with the Liverpool School of Tropical Medicine and St George's at the University of London (https://mologic.co.uk/mologic-and-partners-begin-validation-process-for-covid-19-point-of-need-diagnostic-test/). The validation involved partners worldwide, the Institute Pasteur de Dakar (Senegal), La Jolla Institute for Immunology (US), the Wuhan Institute of Virology (China), the University of Malaya (Malaysia), the Institute for Health Science Research Germans Trias I Pujol (Spain), and the Oswaldo Cruz Foundation (Brazil).