General information and Timelines

This document includes details of the World Health Organization (WHO) SARS-COV-2-antibody- detecting test performance evaluation scheme and criteria for inclusion of products. The SARS-COV-2 antibody-detecting test Performance Evaluation is coordinated by the WHO World Health Emergencies Programme, and includes a number of technical partners such as the National Serology Reference Laboratory, Australia (NRL), the Foundation for Innovative Diagnostics (FIND), Erasmus Medical Centre (EMC), The International Vaccines Institute (IVI) and Duke-NUS Singapore. All product testing will be conducted at the NRL[1]. The operators conducting the evaluation will be identified by the facility management and NRL will provide training on the implementation of the protocol. Only those operators having protocol training by NRL will be authorised to conduct the testing.

A. Introduction

WHO is proposing to undertake evaluations to assess the performance of SARS-COV-2 antibody- detecting assays.

1. **The table below illustrates the number of tests per lot that will be required to be submitted including standard kit contents[1].**

Type of test	Total number of tests required	Number of tests per lot	
		Lot 1	Lot 2
IgG only	880	465	415
IgG and IgM	955	535	420
Semiquantitative[a]	945	513	432

a assay results presented as ratios of specimen signals to the cutoff **values** (**S**/**CO**)

a. Testing will be conducted in two phases:

Phase 1: will be performed against a subset panel of 40 IgG positive and 40 IgM/IgG negative specimen. The results from this phase will detect poor performing test kits and remove them from consideration. To be promoted to phase 2, tests need to achieve at minimum of 80% positivity rate (32 of 40 positive specimens) and < 5% false positive rate (no more than 2 reactive result from 40 negative specimens). Testing of phase 1 specimens will be performed on a single reagent lot.

Phase 2: will be performed against the whole panel containing additional IgG and/or IgM positive and IgG/IgM negative specimens to determine sensitivity and specificity with a greater statistical confidence. If a product does not display sufficient performance against the Phase 1 panel, the product will not be tested against the Phase 2 panel.

[1] In exceptional circumstances another laboratory may be recruited under the supervision of NRL

b. If a test failed phase 1, the results will be shared with manufacturers but will not be published in the main report.

c. Manufacturers are responsible for the supply of test kits and associated reagents, test dependent equipment (if required) and their courier costs and any other associated costs of transport to NRL, including customs and importation fees. There are no other charges associated with the evaluation;

2. The opportunity for submissions of request for inclusion of products (Expression of Interest, EOI) in WHO Performance evaluation will close on 7 December, 2020.

a. Only products listed in the electronic EOI will be eligible for the Performance Evaluation
b. WHO reserves the right to later limit the number of products if the total number of products in the EOI is beyond the capacity for testing (≈ 40 products). Products will be prioritized based on the following criteria:
    i. Format – we are aiming for a 50:50 split between ELISA and rapid diagnostic tests (RDTs)
    ii. independent reports of performance at or above the acceptable performance criteria outlined in the WHO Target Product Profiles for tests for past infection with SARS-CoV-2[2]
    iii. Tests that have more desirable characteristics featured in the TPPs

3. The WHO SARS-COV-2 antibody detecting test performance evaluation will publish the list of products and associated performance data in various formats including:

a. a dedicated WHO website page;
b. electronic and hard copy of compiled performance evaluation results;
c. In advance of all publications, manufacturers will be informed of the performance results, in accordance with the terms of the attached the Confidentiality Agreement

4. Results of the performance evaluation may be used to inform procurement recommendations of WHO and may guide future procurement of SARS-CoV-2 antibody detecting assays by WHO, other UN Agencies and national health authorities.

5. In order for a product to be published in the 'Summary Results' document and published on the WHO website, the product must be commercially available. Products that are not manufactured and/or commercially available will be delisted.

6. The list of submitted products does not in any way imply an endorsement, certification, warranty of fitness or recommendation by WHO of any company or product for any purpose, and does not imply preference over products of a similar nature that are

[2] https://www.who.int/publications/m/item/covid-19-target-product-profiles-for-priority-diagnostics-to-support-response-to-the-covid-19-pandemic-v.0.1 (accessed 17 November, 2020)

not mentioned. WHO furthermore does not warrant that: (1) the list is complete and/or error free; and/or that (2) the products listed are of acceptable quality, have obtained regulatory approval in any country, or that their use is otherwise in accordance with the national laws and regulations of any country, including but not limited to patent laws. Inclusion in the list does not furthermore imply any approval by WHO of the products in question (which is the sole prerogative of national authorities).

7. Participation in WHO SARS-COV-2 performance evaluation scheme and publication by WHO of the testing results may not be used by the manufacturers and suppliers concerned for commercial or promotional purposes. With respect to the manufacturers' or suppliers' participation in the scheme, under no circumstances is a manufacturer or supplier authorized to refer to WHO and/or NRL, the publication of the testing results by WHO and/or NRL and/or inclusion in the website list, in any statement or material of an advertising or promotional nature, press release and/or similar public statement and/or other material aimed at promoting the manufacturer or supplier and/or its products.

B. Criteria for entry to the WHO SARS-COV-2 Antibody detecting assays' performance evaluation scheme and timelines

1. By 7 December, 2020: Submission of an Expression of Interest (EOI) to WHO found at the following link: https://extranet.who.int/dataformv3/index.php/182642?lang=en

2. The EOI requires that the following documents are uploaded:

a) Valid ISO 13485:2003 from all sites where the product(s) is manufactured;

b) Certificate of Free Sale;

c) Submission of scanned original signed copies of the Confidentiality Agreement, and acceptance of conditions for the evaluation and publication of results;

d) Final Product List

i. if the product is available in multiple kit sizes, information for each individual product kit size should be listed

ii. kits containing different or varying formats of components considered different products and may require a separate submission for partial evaluation +/- other supporting documentation. List and specify all product variations in the EOI;

e) Instructions for use (IFU)/package insert of the nominated version of product: Please ensure that instructions uploaded to the EOI form and those that will accompany the assay shipment are accurate and identical. In the case of any discrepancies, the IFU accompanying the assay shipment will apply;

f) Acceptance to the WHO Emergency Use Listing process (pre-submission call and letter of application) contact diagnostics@who.int;

g) Re-labeled products that are manufactured at the same site and under the same conditions as a tested product will not be accepted.

No product assessments will take place unless the manufacturer has fulfilled the above conditions by the dates set by WHO and NRL and in accordance with WHO and NRL's instructions.

3. By 18 December, 2020, manufacturers will receive from WHO, confirmation of inclusion in the evaluation scheme and acceptance of the final list of products.

C. Supply of products for testing

Upon notification of acceptance for inclusion by WHO, NRL will contact the designated person to arrange the collection of information for importation

a) The required number of tests and accompanying standard contents, from each of the two separate lots must be shipped to the NRL, Australia at the address below.

National Serology reference Laboratory, Australia
Attention: Wayne Dimech
4th Floor Healy Building
41 Victoria Parade, Fitzroy 3065
Australia

b) All tests must be received at NRL by COB 1 February, 2020.

c) All products will be stored in an air conditioned, temperature monitored room from the time of receipt until the actual testing occurs.

D. Oversight:
The NRL will maintain the repository of characterized samples against which product assessments will occur, and includes SARS-COV-2 positive samples as well as negative and cross-reacting/interfering samples. A description of the performance evaluation panel are included in the attached protocol.

The NRL will oversee the technical and logistical aspects of the testing and evaluation process, including the development of Standard Operating Procedures (SOPs) and oversight of the product assessment and reporting of results.

E. Further Information
Further information on the WHO SARS-COV-2 Antibody detecting assay's performance evaluation scheme can be found in: Protocol: SARS-COV-2 Antibody Detection Test Kit Performance Evaluation Protocol, World Health Organization and National Serology Reference Laboratory, 2020.