World Health Organization

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WHO INFORMATION NOTICE FOR USERS

Subject: Several falsified in vitro diagnostics (IVDs) for SARS-CoV-2 in the context of COVID-19 testing

Date: 8 April 2020

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Type of action: Advice to end-users of nucleic acid testing assays and serology assays for SARS-CoV-2.

Attention: End-users of IVDs, procurement entities and customs officials, national programme managers and their implementing partners, national regulatory authorities for IVDs.

Purpose: To alert procurers and end-users of IVDs to circulation of falsified SARS-CoV-2 test kits.

Description of the problem:
WHO is receiving continued reports of substandard/falsified test kits claiming to diagnose COVID-19 **or** to detect SARS-CoV-2 or SARS-CoV-2 specific antibodies. Please refer to WHO medical product alert n°3/2020.

Advice for action to be taken by members of the public:
1. Do not purchase test kits for COVID-19 or SARS-CoV-2 online.

Advice on action to be taken by end-users of IVDs for SARS-CoV-2:
1. Follow testing strategies/algorithms for diagnosis of COVID-19 recommended by WHO.
2. Purchase products from a reliable source such as the legal manufacturer, or a reputable economic operator (agent, distributor, supplier, authorized representative).
   a. Ask for copy of the license/certificate giving the supplier rights to sell/distribute the product in your country [1].
   b. Avoid purchasing test kits online from an unknown source.
   c. Contact your regulator if unsure whether the product is of acceptable quality, safety, performance.
   d. Request a copy of the **certificate of analysis from the manufacturer** (not the supplier) for each lot/batch.
   e. Cross-reference the labelling of product received against the approval/authorization letter and labelling on your regulator's website, and the manufacturer's website.
3. Read the instructions for use carefully to understand the intended use of the product.
4. Use Annex 1 to assess, within reasonable doubt, that the product is genuine, and if in doubt please contact WHO.
5. Run quality control materials and enroll in external quality assessment (proficiency testing) schemes.
6. Report any product problems and/or adverse events as complaints to the manufacturer using a complaint form.

Note: For CE-marked products, manufacturers of IVDs for SARS-CoV-2 will self-declare that their product conforms to the European Union IVD regulations meaning they are not required to have a Notified Body (NB) conduct a conformity assessment, as for higher risk IVDs. The CE-mark is affixed without the 4-digit NB number.

Note: Irrespective of the jurisdiction, products may be labelled for research use only (RUO) as they are not strictly intended by their manufacturer for use in human subjects for clinical management. This means the product has not been subjected to the same level of verification and validation studies as would be expected for higher risk products that are regulated for clinical use.

Advice for action to be taken by regulators of IVDs for SARS-CoV-2
1. Refer to WHO's Emergency Use Listing (EUL) for products that meet EUL requirements https://www.who.int/diagnostics_laboratory/EUL/en/
2. Refer to the same webpage, the link to **COVID-19 listing in IMDRF jurisdictions** provides a list of products listed by regulatory authorities in International Medical Devices Regulatory Forum (IMDRF) jurisdictions (Australia, Brazil, Canada, Japan, PR China, Republic of Korea, Russian Federation, Singapore, USA). Please note WHO does not endorse these products, the list is provided for information only.
3. Exchange information with other regulators if market surveillance detects product problems or adverse events.

[1] Some countries may exempt regulatory review of in-house NAT assays for detection of SARS-CoV-2 but would not exempt the need for a license for sale and use of IVD reagents, consumables, and equipment.

Advice for action to be taken by economic operators who wish to supply IVDs for SARS-CoV-2:

1. Follow your usual quality management procedure for verifying key suppliers.
2. Contact your health product regulator who will advise if you should not supply a certain product.

Transmission of this WHO Information Notice for Users:

This notice should be circulated to all those who need to be aware within your organization or to any organization where the potentially affected product has been deployed and used.

Contact person for further information:

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Annex 1 – Identifying features for various types of IVDs for SARS-CoV-2

Nucleic acid testing (NAT) for direct detection of SARS-CoV-2	
Description of assay system	**Physical characteristics**
Closed systems - More often automated technique on one platform/analyzer. - Uses proprietary reagents supplied by a commercial manufacturer (who takes legal responsibility for placing the assay system on the market). - Post-market surveillance is easier to conduct.	• Platform/analyzer likely to be large high-throughput platform for use in laboratories or small low-throughput platform for use at or near to point of care. • Reagents will come in a test kit box.
Open systems - Generally, manual technique on more than one open platform/analyzer. - Uses reagents such as primer/probe sets, and extraction reagents supplied by different commercial or non-commercial manufacturers. - Post-market surveillance is more difficult.	• Typically, only for medium-throughput platforms for use in laboratories. • Reagents will come in one or more small test kit box(es). • Ribonucleic acid (RNA) extraction kit may need to be sourced separately.
In-house assays **(laboratory-developed tests)** - Generally, utilize the same platforms as for open systems. - All reagents must be sourced by the testing laboratory from various suppliers and assay protocol developed from generally non-commercial manufacturers. - Post-market surveillance is exceedingly difficult.	• Typically, only for medium-throughput platforms for use in laboratories. • Reagents will come in one or more small test box(es). • RNA extraction kit and enzyme mixes must be sourced separately.
Serology assays for detection of antibodies to SARS-CoV-2 and SARS-CoV-2 antigen detection	
Random access immunoanalyzer - An automated technique on one platform/analyzer. - Uses proprietary reagents supplied by a commercial manufacturer (who takes legal responsibility for placing the assay system on the market). - Post-market surveillance is easier to conduct.	• Platform/analyzer likely to be large high-throughput platform for use in laboratories.
Manual loaded microtiter plate enzyme immunoassay (EIA) - Uses general laboratory equipment (incubator, washer/vacuum, spectrophotometer). - Uses proprietary reagents supplied by a commercial manufacturer (who takes legal responsibility for placing the assay system on the market). - Post-market surveillance is easier to conduct.	• Equipment allows for medium-throughput in laboratories. • Reagents are packaged in kits of 96 tests (or multiples thereof).
Rapid diagnostic test (RDT) - Usually immunochromatographic format. - Supplied by a commercial manufacturer (who takes legal responsibility for placing the assay system on the market). - Post-market surveillance is easier to conduct.	• Single-use device allows for use in low-throughput settings, at or near to point of care. • Usually cassette format.