



وزارت بهداشت، درمان و آموزش پزشکی

معاونت غذا و دارو

تاریخ: ۱۳۹۹/۰۳/۱۲
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پیوست: ندارد

بسم الله الرحمن الرحيم

آنی

رئیس محترم مرکز آموزشی درمانی: امام رضا (ع) شهدا شهدا ۱ شهید مدنی سینا الزهرا(س) علوی طالقانی نیکو کاری کودکان رازی و مجتمع باباباگی اسدآبادی دکتر لک

سرپرست محترم شبکه بهداشت و درمان شهرستان: آذرشهر اسکو اهر بستان آباد بناب جلفا سراب شبستر کلیبر مرند ملکان میانه ورزقان هریس هشتروند چاراویماق عجبشیر

ریاست محترم بیمارستان: استاد عالی نسب ۲۹ بهمن ۵۲۲ ارتش الغدیر شهید محلاتی امیرالمومنین (ع) شمس شهریار شفا نورنجات بهبود گروه پزشکی ولیعصر حکیمان نور مهر امام سجاد (ع) آبان فجر

موضوع: به پیوست اطلاع رسانی سازمان جهانی بهداشت در خصوص کیت قلبی تشخیص سارس کووید-۲

با سلام و احترام؛

به پیوست نامه شماره ۶۵۸/۲۱۵۰۸ مورخ ۱۳۹۹/۰۳/۰۶ مدیر کل محترم دفتر نظارت و پایش مصرف فرآورده های سلامت در خصوص کیت قلبی تشخیص سارس کووید-۲ جهت بهره برداری های لازم ایفاد میگردد.

دکتر محبوب نعمتی
معاون غذا و دارو دانشگاه

رونوشت:

جناب آقای دکتر بهزاد میلی مدیر محترم امور آزمایشگاه های استان آذربایجان شرقی: جهت استحضار
جناب آقای دکتر هادی همیشه کار مدیر نظارت و ارزیابی تجهیزات و ملزومات پزشکی دانشگاه: جهت استحضار

تبریز- کمربند میانی- میدان پیشقدم- خیابان ملاصدرا- پردیس شماره ۲ دانشگاه علوم پزشکی تبریز

کدپستی ۵۱۶۵۹۹۴۶۱۱ تلفن ۳۱۷۷۳۳۳۸ تلفن میز خدمت ۳۱۷۷۳۳۳۹ نمابر ۳۱۷۷۳۳۴۵

شماره ۱۳۵/۴۳۰
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پوست ندارد

جناب آقای دکتر رئیسی

معاون محترم بهداشت

جناب آقای دکتر شانه ساز

معاون محترم وزیر و رئیس سازمان غذا و دارو

سلام علیکم

بااحترام، به پیوست تصویر نامه شماره ۴/۱۸ مورخ ۱۳ آوریل ۲۰۲۰ دفتر نمایندگی سازمان جهانی بهداشت در ج.ا.ایران در خصوص " هشدار آن سازمان در مورد کیت In Vitro تقلبی SARS-Cov-2 جهت تشخیص COVID-19 (CRM:0003936) جهت استحضار ایفاد می گردد.
باعنایت به اینکه آن سازمان در نظر دارد، هشدار بین المللی و آگاهی در خصوص کیت تشخیصی تقلبی SARS-Cov-2 را که در بازار موجود می باشد، را افزایش دهد. لذا خواهشمند است دستور فرمایید، نسبت به هماهنگی های لازم جهت اطلاع رسانی موضوع فوق به واحدهای های ذیربط اقدام مقتضی معمول و از نتیجه این حوزه را در اسرع وقت مطلع نمایند.
ضمناً هشدار آن سازمان در خصوص کیت مذکور به پیوست ایفاد می گردد.

دکتر محسن اسدبی لاری
مدیر کل همکاری های بین الملل

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13 April 2020

Information Notice on Falsified In Vitro Diagnostics (IVDs) for SARS-CoV-2 in the Context of COVID-19 Testing CRM:0003936


Dear Dr Asadi Lari,

I am writing to bring to your kind attention about a WHO medical product alert relating to falsified In Vitro Diagnostics (IVDs) for SARS-CoV-2 in the context of COVID-19 testing.

The related WHO Global Medical Product Alert is enclosed for your information and further dissemination to the respected departments/entities such as Expanded Program on Immunization (EPI) Department, National Regulatory Authority, Procurement institution/department.

Thank you,

Yours sincerely,

 Dr Christoph Hamelmann
WHO Representative
I.R. Iran



Dr Mohsen Asadi Lari
Director General for International Affairs
MOHME, I.R. Iran

CC: Dr Hamidreza Inanloo
Director General, International Relations Department
Food and Drug Administration

Encs. As stated above



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

WHO-identifier: 2020/2, version 2

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 country¹.
 - 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:

Anita SANDS, Regulation and Safety Unit, World Health Organization, e-mail: sandsa@who.int

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 <ul style="list-style-type: none"> - 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. | <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> - 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. | <ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> - 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. | <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> - 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. | <ul style="list-style-type: none"> • Platform/analyzer likely to be large high-throughput platform for use in laboratories. |
| Manual loaded microtiter plate enzyme immunoassay (EIA) <ul style="list-style-type: none"> - 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. | <ul style="list-style-type: none"> • Equipment allows for medium-throughput in laboratories. • Reagents are packaged in kits of 96 tests (or multiples thereof). |
| Rapid diagnostic test (RDT) <ul style="list-style-type: none"> - 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. | <ul style="list-style-type: none"> • Single-use device allows for use in low-throughput settings, at or near to point of care. • Usually cassette format. |