Health Alert Network

Tri-County Health Department
Serving Adams, Arapahoe and Douglas Counties
Phone 303/220-9200 • Fax 303/741-4173 • www.tchd.org
Follow us on Twitter @TCHDHealth
John M. Douglas, Jr., M.D. Executive Director

The pages that follow contain information critical to protecting the health of your patients and the citizens of Colorado.

HAN ADVISORY

Number of pages including cover: 5

Subject: **Advisory – List of COVID-19 Antibody Tests that should no longer be used in the U.S.**
Message ID: 5/27/2020 10:00 AM
Recipients: HAN Community Members.
From: TRI-COUNTY HEALTH DEPARTMENT
Adams, Arapahoe and Douglas County, Colorado

Recipient Instructions: **Tri-County Health Department is sending you the attached HAN. Providers, please distribute widely in your offices. No response required.**

For more information:

- TCHD COVID-19 web page: http://www.tchd.org/818/Coronavirus-COVID-19
- CDPHE COVID-19 web page: https://covid19.colorado.gov/
- CDC COVID-19 web page: https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Medical resource requests/questions may be submitted to Logistics@tchd.org. TCHD Logistics will provide the ordering resource document (213RR) and direct partners to the corresponding County or City OEM Logistics personnel to place your orders into the State ordering system, Web EOC.
- For questions about COVID-19 please call Tri-County Health Department at 303-220-9200 or callcenter@tchd.org
- Members of the public may contact CO Help at 303-389-1687 or 1-877-462-2911 with general questions about COVID-19 to receive answers in many languages including English, Spanish (Español), Mandarin (普通话), and more, or email COHELP@RMPDC.org (for answers in English only).

==========

Categories of Health Alert Network Messages:

Health Alert: Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: Provides important information for a specific incident or situation; may not require immediate action.
Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.
Info Service/Public Health Brief: Provides general information that is not necessarily considered to be of an emergent nature.

You may download a copy of this HAN from the TCHD website at
http://www.tchd.org/259/Health-Alert-Network

Tri-County Health Department
Serving Adams, Arapahoe and Douglas Counties

HEALTH ADVISORY List of COVID-19 Antibody Tests that should no longer be used in the U.S.

Health care providers: Please distribute widely in your office

Key points

- On May 21, 2020, the U.S. Food and Drug Administration (FDA) posted a list of antibody tests that are being removed from the "notification list" of tests being offered under the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency.
- Antibody tests on this removal list are those which have been voluntarily withdrawn by the test's commercial manufacturer and those for which there is not a pending Emergency Use Authorization (EUA) request or issued EUA. It is expected that this removal list will continue to be updated.
- Health care providers and local laboratories should no longer use the antibody tests removed from the FDA notification list. Health care providers and local laboratories should review this list regularly.
- Published scientific data are insufficient to determine whether serologic assays can or should be used to diagnosis COVID-19. Additionally, it is unknown whether having IgG antibodies against COVID-19 means that the person has developed protective immunity and cannot be reinfected. Until more studies are completed, results from serologic tests should not be used to make decisions about disease control (e.g., stop wearing PPE). CDC is evaluating the performance of several commercially manufactured antibody tests for SARS-CoV-2 in collaboration with other federal organizations; results from these studies are pending.

Background

On May 21, 2020, the U.S. Food and Drug Administration (FDA) posted a list of antibody tests that are being removed from the "notification list" of tests being offered under the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency.

Antibody tests on this removal list are those which have been voluntarily withdrawn by the test's commercial manufacturer and those for which there is not a pending Emergency Use Authorization (EUA) request or issued EUA. The commercial antibody tests on the removal list are noted in the table below (as of May 22, 2020); it is expected that this removal list will continue to be updated.

The FDA expects that the tests on the removal list now and in the future will not be marketed or distributed in the U.S.

In early May, the FDA issued revised recommendations/expectations for commercial manufacturers of antibody tests to submit test validation data and EUA request. Under this revised policy, the FDA outlined the following expectations:

- Commercial manufacturers will submit EUA requests, with their validation data, within 10 business days from the date they notified the FDA of their validation testing OR from the date of this policy, whichever is later.
- Furthermore, the FDA has provided specific performance threshold recommendations for specificity and sensitivity for all serology test developers.
- The EUA request allows the FDA is able to examine data on the test's performance and make a formal determination of whether to authorize it for emergency use, because EUAs give labs and health care professionals the confidence that the FDA has reviewed a particular test.

If an EUA request is not submitted by a commercial manufacturer of a serology test within a reasonable period of time, or if significant problems are identified with such a test that cannot be or have not been addressed in a timely manner, FDA intends to remove the manufacturer and test from the notification list. It is not accurate for developers to claim their test was authorized by the FDA if an EUA was not granted for the tests, nor should they be distributing their test if it has not been properly validated.

CDC is evaluating the performance of commercial antibody tests

CDC is evaluating the performance of several commercially manufactured antibody tests for SARS-CoV-2 antibodies available through healthcare providers and commercial laboratories in collaboration with the following federal organizations:

- Biomedical Advanced Research and Development Authority
- U.S. Food and Drug Administration (FDA)
- National Institutes of Health
- Department of Defense
- White House Office of Science and Technology Policy

Results from the initial federal evaluation are included in FDA's EUA Authorized Serology Test Performance and will be updated as more tests are evaluated.

What commercial manufactures of serological tests had previously provided notification to the FDA under the policy outlined in Section IV.D of the Policy for Coronavirus Disease-2019 Tests but have now been removed from that notification list? (Updated 5/22/2020)

The FDA expects that the tests on the removal list now and in the future will not be marketed or distributed in the U.S.

Manufacturer	Test
Anhui Deepblue Medical Technology Co., Ltd.	COVID-19 (SARS-CoV-2) IgG/IgM Antibody Test Kit (Colloidal Gold)
Artron BioResearch Inc./ Artron Laboratories Inc.	COVID-19 IgM/IgG Antibody Test
BestNovo (Jiangsu) Medical Technology Co., Ltd.	BestNovo COVID-19 IgM/IgG Antibody Rapid Test Kit
Biobase Biodustry (Shandong) Co., Ltd.	SARS-CoV-2 IgM/IgG Antibody Test Kit (Colloidal Gold)
BioMedomics, Inc.	COVID-19 IgM-IgG rapid test
Bioscience(Chongqing) Diagnostic Technology Co., Ltd.	Qualitative Diagnostic Kit for Novel Coronavirus (2019-nCoV) IgM Antibody
Bioscience(Chongqing) Diagnostic Technology Co., Ltd.	Qualitative Diagnostic Kit for Novel Coronavirus (2019-nCoV) IgG Antibody
Bioscience(Tianjin) Diagnostic Technology Co., Ltd.	Qualitative Diagnostic Kit for Novel Coronavirus(2019-nCoV) IgM Antibody
Bioscience(Tianjin) Diagnostic Technology Co., Ltd.	Qualitative Diagnostic Kit for Novel Coronavirus(2019-nCoV) IgG Antibody
Boson Biotech Ltd. Co (Distributed by Pure Genetic Medical Ltd.)	Rapid 2019-nCoV IgG/IgM Combo Test Card
Changchun Wancheng Bio-Electron Co., Ltd.	COVID-19 IgG/IgM ANTIBODY RAPID TEST KIT (Colloidal gold immunochromatography)
Diazyme Laboratories, Inc.	Diazyme SARS-CoV-2 Antibody Rapid Test
Genlantis Diagnostics, Inc.	CovidQuik Coronavirus (COVID-19) IgM/IgG Antibody Test
Hangzhou Clongene Biotech Co., Ltd.	COMBRA COVID-19 IgM/IgG Rapid Test Cassette
Hangzhou Testsea Biotechnology Co., Ltd.	One Step SARS-CoV2(COVID-19) IgG/IgM Test
Hunan RunKun Pharmaceutical Co., Ltd.	SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)

Manufacturer	Test
IMMY, Inc.	clarus SARS-CoV-2 Total Antibody EIA
Jiangsu Eubo Biotechnology Co., Ltd.	EUBO COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)
Lifeassay	Test-it COVID-19 IgM/IgG Lateral Flow Assay
Phamatech	COVID19 IgG / IgM Rapid Test
Promedical	COVID-19 Rapid Test
Saladax Biomedical	COVID-19 IgG/IgM Rapid Antibody Test
Shanghai Eugene Biotech Co., Ltd.	SARS-CoV2 (COVID-19) IgG/IgM Rapid Test
Shenzen Landwind Medical Co., Ltd.	COVID-19 IgG/IgM Rapid Test
VITA Testing	COVID-19 IgM/IgG Antibody Rapid Test Kit
Zhengzhou Fortune Bioscience Co., Ltd.	COVID-19 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography Method)
Zhengzhou Fortune Bioscience Co., Ltd.	COVID-19 IgM Antibody Rapid Test Kit
Zhengzhou Fortune Bioscience Co., Ltd.	COVID-19 IgG Antibody Rapid Test Kit
Zhongshan Bio-Tech Co Ltd.	SARS-CoV-2 IgM/IgG (GICA)

Information extracted from these websites:

FDA:

- www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy
- www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-promised-transparency-antibody-tests
- (antibody tests removed from FDA notification list) www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2
- www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised

CDC:

- www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html