

(U//FOUO) Scope Note: This product is based on raw field intelligence, open source, intelligence community, and other information, to include law enforcement sensitive information. It focuses on strategic warning and operational emerging threats as well as opportunity analysis to further CBP and national security interests. Topics featured include items with a nexus to CBP's mission that are enhanced by CBP data and analytics.

(U) Trade: Non-FDA Approved COVID-19 Test Kits Shipped to the United States

(U) *As a surge in the demand for medical supplies occurs amidst the outbreak of COVID-19, a range of bad actors, including opportunists, Transnational Criminal Organizations, and state actors, may seek to exploit the situation by attempting to introduce bogus or non-U.S. Food and Drug Administration (FDA) approved COVID-19 test kits into the U.S. marketplace.* As of 18 March, there have been a total of 207,860 confirmed COVID-19 cases, in 166 countries (areas or territories), and a total of 8,657 deaths, as reported by ArcGIS^{USBUS}. While the United States has 7,087 confirmed cases, ranked at number eight, the top five countries with the most cases are: 1) China: 81,174; 2) Italy: 35,713; 3) Iran (Islamic Republic of): 17,361; 4) Spain: 13,716; and 5) Germany: 8,198.¹ In early February 2020, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency because of the COVID-19 virus, and that circumstances justified the authorization of emergency use of in-vitro diagnostics for detection and/or diagnosis of the novel coronavirus – COVID-19, according to the FDA.² Because of the spread of the virus, as well as the spread of fear and panic, there has also been a surge in the demand for medical supplies and equipment. The sudden increase in demand has created an opportunity for a range of bad actors to introduce bogus, and potentially unsafe products, into the U.S. market.

- (U//LES) On March 15, a Cargo Control and Enforcement CBP Officer (CBPO) targeted a shipment at DHL Express at John F. Kennedy International Airport manifested as “RAPID TEST KITS”, arriving from Hong Kong and destined for Queens, New York, according to CBP reporting. CBPOs examined the shipment and discovered one box containing, what purported to be, 200 Coronavirus test kits. The FDA was notified and determined the test kits were subject to FDA refusal because test kits manufactured by this facility are not registered with the FDA to produce any type of medical product. The test kits were seized for a number of trade violations to include



(U) Figure 1: Non-FDA approved COVID-19 Test Kits at JFK

misbranding and adulteration. Homeland Security Investigations (HSI) responded and an investigation is ongoing.³

- (U) On 12, 13, and 16 March, CBP Officers (CBPOs) assigned to the Los Angeles International Airport (LAX), International Mail Facility (IMF), seized parcels arriving from Exeter, United Kingdom as part of an operation to intercept medications claiming to cure COVID-19, according to CBP reporting. All three shipments were from the same shipper, Lifework Potential Limited, and manifested as “purified water vials”. The 12 March seizure consisted of six plastic bags containing various test vials. The plastic bags contained labels for “Corona Virus 2019nconv (COVID-19)” and “Virus1 Test Kit”.⁴ The 13 March seizure consisted of various plastic bags containing test vials with a clear liquid inside. One of the plastic bags contained a vial with a “Corona Virus 2019nconv (COVID-19) Test Kit” label.⁵ On 16 March, the physical examination of the parcels resulted in the discovery of various plastic bags containing test vials with clear liquid inside. The plastic bags contained vials with a “Corona Virus 2019nconv (COVID-19)” label.⁶ However, it should be noted that authorized diagnostic testing for COVID-19 is only conducted in verified state and local public health laboratories across the United States. The shipments were suspected of being non-FDA approved test kits and turned over to the FDA for analysis.⁷



(U) Figure 2: Suspected Counterfeit COVID-19 Test Kits at LAX IMF
CBP

(U) *CBP OI notes that NTC-Cargo T3U has created User Defined Rules (UDRs) and a trade alert in order to identify and seize future non-FDA approved COVID-19 test kits. Furthermore, the FDA has issued guidance to laboratories and commercial manufacturers to accelerate the diagnostic development and widespread testing capacity within the United States.⁸ According to FDA reporting, on 16 March, the FDA announced Emergency Use of Authorization (EUA) to Hologic^{USBUS} and Laboratory Corporation of America^{USBUS}.⁹ The FDA has also given emergency clearance for tests made by Roche^{USBUS} and Thermo Fisher^{USBUS}, as reported by Axios.¹⁰ The President and CEO of Roche Diagnostics North America^{USBUS}, expressed appreciation for the FDA's efforts to accelerate the process to grant EUA for the tests and added that the company began shipping test kits immediately so labs could start to offer high-volume testing as soon as possible and give more patients access to reliable diagnostics.¹¹ Earlier this month, the HHS Assistant Secretary reported that more than 1 million tests are expected to come on board this week.¹² Medicare has released the prices of COVID-19 tests, noting that the prices are \$35.92 USD for the tests developed by the Center for Disease Control and Prevention and \$51.33 USD for all other commercial tests.¹³*

(U) *CBP OI assesses that as the number of confirmed COVID-19 cases grow, opportunistic state actors and criminal actors may exploit the public's fears for financial gain through an increase of non-FDA approved COVID-19 test kits or other illegitimate products. Rapid detection of COVID-19 cases in the United States requires wide availability of diagnostic*

UNCLASSIFIED//LAW ENFORCEMENT SENSITIVE

testing to control the emergence of this rapidly spreading severe illness, according to the FDA.¹⁴

(U) BID Submissions: If you have a good news story or information that would be beneficial to CBP leadership or the field, please submit a draft article, contextual or analytical comments and supporting sources to cbpsiadb@cbp.dhs.gov

(U) Warning: The information contained herein remains under the control of the Department of Homeland Security (DHS), through U.S. Customs and Border Protection (CBP). It is disseminated for law enforcement purposes only.

(U) This document may contain information that is UNCLASSIFIED//LAW ENFORCEMENT SENSITIVE (U//LES). It contains information that may be exempt from public release under the Freedom of Information Act (5 U.S.C. § 552). It is to be controlled, stored, handled, transmitted, distributed, and disposed of in accordance with DHS policy relating to FOUO information and is not to be released to the public, the media, or other personnel who do not have a valid need-to-know without prior approval of an authorized CBP official.

(U) This Product may contain U.S. Persons information deemed necessary for the intended recipient to understand or assess the information provided. The information has been highlighted in the document with the label USPER, pursuant to E.O. 12333 that affords protections for U.S. persons.

¹ (U) Our World in Data | 17 March 2020 | (U) Coronavirus Research and Statistics | Accessed on 18 March 2020 | Extracted information classification is U | Overall document classification is U

| <https://experience.arcgis.com/experience/685d0ace521648f8a5beeee1b9125cd>

² (U) U.S. Food and Drug Administration | 16 March 2020 | (U) Policy for Diagnostic Tests for Coronavirus Disease -2019 during the Public Health Emergency | Accessed on 18 March 2020 | Extracted information classification is U | Overall document classification is U | <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency>

³ (U//LES) CBP | Email exchange with CBP Watch Commander at JFK and CBP Office of Intelligence New York Field Intelligence Group | 17 March 2020 | Updated Local Report: JFK Cargo seizure of 200 Coronavirus Test Kits / HSI investigation ongoing | Extracted information classification is U//LES | Overall document classification is U//LES

⁴ (U//LES) | CBP | 17 March 2020 | Email | (U//LES) FW: Situational Awareness: IMF Seizure of Counterfeit COVID-19 test kits | Accessed on 19 March 2020 | Extracted information classification is U//LES | Overall document classification is U//LES

⁵ (U//LES) | CBP | 13 March 2020 | Email | (U//LES) Situational Awareness: International Mail Facility (IMF) Intercepts Possible Counterfeit COVID-19 Test Kit from United Kingdom (U.K.) | Accessed on 19 March 2020 | Extracted information classification is U//LES | Overall document classification is U//LES

⁶ (U//LES) | CBP | 16 March 2020 | Email | (U//LES) Los Angeles, CA: International Mail Facility (IMF) Intercepts Possible Counterfeit COVID-19 Test Kits from United Kingdom (U.K.) | Accessed on 19 March 2020 | Extracted information classification is U//LES | Overall document classification is U//LES

⁷ (U) | CBP | 14 March 2020 | (U) CBP Officers Seize Fake COVID-19 Test Kits at LAX | Accessed on 16 March 2020 | Extracted information classification is U | Overall document classification is U | <https://www.cbp.gov/newsroom/national-media-release/cbp-officers-seize-fake-covid-19-test-kits-lax>

⁸ (U) U.S. Food and Drug Administration | 16 March 2020 | (U) Policy for Diagnostic Tests for Coronavirus Disease -2019 during the Public Health Emergency | Accessed on 18 March 2020 | Extracted information classification is U | Overall document

UNCLASSIFIED//LAW ENFORCEMENT SENSITIVE

classification is U | <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency>

⁹ (U) Food and Drug Administration Online | 16 March 2020 | (U) COVID-19 Update: FDA Issues Diagnostic Emergency Use Authorization to Hologic and LabCorp | Accessed on 19 March 2020 | Extracted information classification is U | Overall document classification is U | <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-diagnostic-emergency-use-authorization-hologic-and-labcorp>

¹⁰ (U) Axios | 17 March 2020 | (U) Coronavirus Testing is Getting Better | Accessed on 18 March 2020 | Extracted information classification is U | Overall document classification is U | <https://wwwaxios.com/coronavirus-testing-is-getting-better-a1d86956-37f6-4e30-af19-f3a62e7838f0.html>

¹¹ (U) Roche Diagnostics | 2020 | (U) Roche begins shipments of first 400,000 COVID-19 tests to laboratories across US to begin patient testing under FDA Emergency Use Authorization | Accessed on 18 March 2020 | Extracted information classification is U | Overall document classification is U | <https://diagnostics.roche.com/us/en/news-listing/2020/roche-begins-shipments-of-first-400000-covid-19-tests-to-laboratories-across-US-to-begin-patient-testing-under-fda-emergency-use-authorization.html>

¹² (U) Axios | 13 March 2020 | Price of the CDC Coronavirus Test Kit: \$36 | Accessed on 17 March 2020 | Extracted information classification is U | Overall document classification is U | <https://wwwaxios.com/medicare-price-cdc-coronavirus-test-b11170ec-9d40-494f-a3b0-db5005cb7377.html>

¹³ (U) Axios | 13 March 2020 | Price of the CDC Coronavirus Test Kit: \$36 | Accessed on 17 March 2020 | Extracted information classification is U | Overall document classification is U | <https://wwwaxios.com/medicare-price-cdc-coronavirus-test-b11170ec-9d40-494f-a3b0-db5005cb7377.html>

¹⁴ (U) U.S. Food and Drug Administration | 16 March 2020 | (U) Policy for Diagnostic Tests for Coronavirus Disease -2019 during the Public Health Emergency | Accessed on 18 March 2020 | Extracted information classification is U | Overall document classification is U | <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency>