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VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this Citizen Petition pursuant to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and in accordance with 21 C.F.R. §§ 10.25(a) and 10.30, to request the U.S. Food and Drug Administration (FDA) take additional administrative action with respect to the agency's policy on screening and surveillance tests during the COVID-19 public health emergency. The issues involved, relevant facts, and applicable law and policy are provided below.

A. Action Requested

The undersigned respectfully requests that during the COVID-19 public health emergency, FDA take additional administrative action to further protect public health by permitting facilities, such as workplaces and schools, to use "screening tests," including noninvasive or minimally invasive molecular in vitro screening tests, in combination with other allowable screening methods, to improve facilities' ability to prevent COVID-19 transmission, even if the screening tests are not authorized by FDA. Because results of screening tests cannot be shared with individuals until confirmed by a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA),[1] the undersigned requests that during the COVID-19 public health emergency, FDA permit facilities to use "screening tests" under the same policy that "surveillance tests" are permitted.

[1] 42 U.S.C. § 263a.

B. Statement of Grounds

1. Current FDA Policy Distinguishes Between Screening Tests and Surveillance Tests

On February 4, 2020, the Secretary of Health and Human Services determined that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, involving SARS-CoV-2, the virus that causes COVID-19.[2] On the basis of that determination, the Secretary declared that circumstances exist to justify the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of SARS-CoV-2.[3] FDA acted quickly, and on February 29, 2020, issued guidance that provides policy intended to help accelerate the availability of COVID-19 tests during this public health emergency.[4] The agency updated this guidance document on March 16, May 4, and May 11, 2020. In addition to this guidance, FDA developed and has regularly updated a Frequently Asked Questions (FAQ) resource, which "provides answers to frequently asked questions relating to the development and performance of tests for SARS-CoV-2. These questions and answers provide additional clarity on existing policies and do not introduce any new policies or modify any existing policies."[5]

In its FAQ resource, FDA distinguishes between three types of tests for SARS-CoV-2: diagnostic tests, screening tests, and surveillance tests. In response to the question, "What is the difference between surveillance, screening, and diagnostic testing for COVID-19 testing?" the agency states that diagnostic tests for COVID-19 look "for occurrence at the individual level," but are "performed when there is a particular reason to suspect that an individual may be infected."[6] These tests "are intended to diagnose an infection in patients suspected of COVID-19 by their healthcare provider."[7]

Screening tests "are intended to identify infected individuals prior to development of symptoms or those infected individuals without signs or symptoms who may be contagious,

[2] Determination of Public Health Emergency, 85 Fed. Reg. 7316 (Feb. 7, 2020).
[3] *Id.* at 7316-17.
[4] *See* FDA, "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised): Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff" (May 11, 2020), *available at* https://www.fda.gov/media/135659/download.
[5] FDA, "FAQs on Testing for SARS-CoV-2," *at* https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2 (last visited Oct. 6, 2020).
[6] *See* FDA, "FAQs on Testing for SARS-CoV-2: What is the difference between surveillance, screening, and diagnostic testing for COVID-19 testing?" (July 2, 2020), *at* https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general (last visited Oct. 6, 2020) [hereinafter FDA, "COVID-19 Testing FAQ"].
[7] *Id.*

so that measures can be taken to prevent those individuals from infecting others."[8] Screening tests look "for occurrence at the individual level even if there is no individual reason to suspect infection such as a known exposure. This includes broad screening of asymptomatic individuals *without known exposure* with the intent of making individual decisions based on the test results."[9] FDA provides examples of screening tests, which include:

> testing plans developed by a workplace to test all employees returning to the workplace regardless of exposure or signs and symptoms and testing plans developed by a school to test all students and faculty returning to the school regardless of exposure or signs and symptoms, with the intent of using those results to determine who may return or what protective measures to take on an individual basis.[10]

Surveillance tests are described by FDA as tests "generally used to monitor for an occurrence, such as an infectious disease outbreak, in a population or community, or to characterize the occurrence once detected, such as looking at the incidence and prevalence of the occurrence."[11] While screening tests are intended to identify information at the individual level, surveillance tests are "primarily used to gain information at a population level," and may be "random sampling of a certain percentage of a specific population to monitor for increasing or decreasing prevalence and determining the population effect from community interventions such as social distancing."[12] FDA's example of surveillance testing is "a testing plan developed by a State Public Health Department to randomly select and sample 1% of all individuals in a city on a rolling basis to determine local infection rates and trends."[13] FDA notes that it does not generally regulate surveillance testing.[14] Thus, surveillance tests for SARS-CoV-2 are not generally subject to FDA's current Emergency Use Authorization (EUA) process.

With respect to both screening and surveillance tests for SARS-CoV-2, FDA states that "[i]f at any time a patient specific result is to be reported by a facility, it must first obtain a CLIA certificate and meet all [CLIA] requirements to perform testing."[15] Interestingly, FDA's description of both screening and surveillance tests for SARS-CoV-2 cites the Centers for

[8] *Id*.
[9] *Id*. (emphasis in original).
[10] *Id*.
[11] *Id*.
[12] *Id*.
[13] *Id*.
[14] *Id*.
[15] *Id*.

Medicare & Medicaid Services' (CMS') Frequently Asked Questions resource regarding surveillance testing.[16] In this document, CMS states:

> During this COVID-19 Public Health Emergency, facilities performing SARS-CoV-2 surveillance testing using a pooled sampling procedure to report **non patient-specific** SARS-CoV-2 cohort results will not require CLIA certification. This testing is not considered diagnostic of SARS-Cov-2 infection, and participants should not rely on information received from this type of testing for decision making purposes.
>
> If at any time a **patient specific result** is to be reported by your facility, you **must first** obtain a CLIA certificate and meet all requirements prior to testing.[17]

Though screening tests do not use pooled samples, screening tests and surveillance tests for SARS-CoV-2 share common characteristics under both FDA and CMS policy. Patient-specific (i.e., individual) results cannot be provided, and a diagnostic decision cannot be made, at a facility in real time. In fact, no individual results from either screening tests or surveillance tests can be provided to individuals until and unless the results are confirmed at a CLIA-certified laboratory. As described below, the characteristics shared by screening tests and surveillance tests are relevant for facilities focused on preventing the transmission of COVID-19 during this public health emergency.

To better prevent COVID-19 transmission, facilities need ongoing, repetitive screening tests. The high demand, which continues to increase as more facilities open, can and is outpacing available screening tests with EUAs, despite the rate at which FDA is authorizing SARS-CoV-2 tests.

2. Facilities Seek Increased Access to Additional Screening Tests, which are Crucial for Public Health

As the COVID-19 public health emergency continues, and facilities such as workplaces and schools re-open, screening solutions that allow rapid and confident decisions to reduce transmission of the SARS-CoV-2 virus are crucial to public health. Many facilities presently rely on temperature checks with electronic thermometers, oxygen saturation levels with pulse oximeters, questionnaires regarding activities and travel, and/or observed symptoms

[16] *See* CMS, "Frequently Asked Questions: SARS-CoV-2 Surveillance Testing" (June 19, 2020), *at* https://www.cms.gov/files/document/06-19-2020-frequently-asked-questions-covid-surveillance-testing.pdf.
[17] *Id*. (emphases in original).

such as coughing as screening tools to make decisions. These screening methods relate to common symptoms of COVID-19, and do not screen for the actual SARS-CoV-2-virus. Such screening methods provide less information and are less ideal than rapid, onsite testing for SARS-CoV-2.

Moreover, screening tools such as electronic thermometers are not subject to regulation by FDA, and many pulse oximeters are also not authorized by the agency.[18] However, facilities are using the information provided by these tools and others to make decisions regarding the presumptive COVID-19 status of individuals prior to allowing entry, and not all cases are followed up with testing at a laboratory. Many facilities need and/or would like to use additional screening methods, including onsite molecular in vitro screening tests, for SARS-CoV-2. Screening tests have the potential to provide more accurate and more meaningful information to facilities to help prevent COVID-19 transmission than the tools widely used to measure common symptoms.

As described above, FDA policy pertaining to SARS-CoV-2 tests describes diagnostic tests, screening tests, and surveillance tests. Under the agency's policy, individual (or patient-specific) results cannot be reported for any type of test unless the test is performed at a CLIA-certified laboratory. However, between diagnostic, screening, and surveillance tests, only surveillance tests can be performed without general regulation by FDA.[19] Thus, screening tests are generally subject to FDA regulation, currently through EUAs.

From the perspective of many facilities, "screening tests" and "surveillance tests" should not be treated differently under FDA policy because: (a) both types of tests require confirmation from a CLIA-certified laboratory before individual test results can be provided to an individual; (b) facilities are not providing individuals with test results onsite in real time; and (c) other screening is currently permitted under FDA policy with devices that are not authorized by the agency, such as electronic thermometers and pulse oximeters. In the midst of the current public health emergency, the distinction between screening and surveillance

[18] *See*, *e.g.*, FDA, "Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff" (April 2020), at 3 ("during the public health emergency, FDA does not intend to object to the distribution and use of clinical electronic thermometers that are not currently 510(k) cleared" if these devices "do not create an undue risk in light of the public health emergency") *available at* https://www.fda.gov/media/136698/download. Additionally, while many oximeters are subject to premarket clearance and other FDA requirements under 21 C.F.R. § 870.2700, during the current public health emergency, facilities are using the oximeters that are easier to access. These oximeters are not reviewed by the agency and are usually labeled "not for medical use."

[19] *See* FDA, "COVID-19 Testing FAQ," *supra* note 6. This petition does not apply to screening tests that qualify as laboratory developed tests.

tests has resulted in an FDA policy that is not serving the imminent public health need of facilities.

3. For Facilities, Screening Tests and Surveillance Tests Share Common Elements and Should not be Treated Differently Under FDA Policy During This Public Health Emergency

FDA's distinctions between diagnostic, screening, and surveillance tests in its FAQ for COVID-19 testing are consistent with accepted scientific and public health categorization of tests generally. As described in Section B.1 of this petition, screening tests are distinguished from surveillance tests by the intended use, i.e., to identify infected individuals before the development of symptoms versus gaining information at a population level. The undersigned recognizes and understands this generally accepted distinction.

However, to help prevent transmission of COVID-19, facilities should be permitted to use "screening tests" under the same policies that "surveillance tests" are permitted to be used, i.e., even if a screening test is not authorized by FDA. The request for additional administrative action during the COVID-19 public health emergency in this petition may seem inconsistent with the generally accepted categorizations of and differences between screening and surveillance tests. But, as stated above, the distinction between screening and surveillance tests has resulted in an FDA policy distinction that is not serving the imminent public health need for facilities during the COVID-19 public health emergency.

Many screening tests are being developed that are intended to quickly produce a visual result, which can then be verified by a CLIA-certified laboratory. With proper protocols in place, such screening tests can enhance and improve facilities' prevention efforts, without compromising FDA's underlying policy goals for SARS-CoV-2 testing, i.e., individual results are not provided to individuals until performed at a CLIA-certified laboratory. A protocol for onsite screening tests could include the following elements:

- Each individual's information must be linked to a unique code. An individual's information will only be available to the CLIA-certified laboratory.

- An individual's sample is collected pursuant to the instructions for the particular screening test. The sample collection method must be either noninvasive or minimally invasive.

- The sample will be tested onsite pursuant to the instructions for the particular screening test, but out-of-sight of any individuals being tested.

- In addition to the screening test, each individual must undergo another screening method, such as a temperature check, measurement of oxygen saturation, questions about exposure, etc.

- Samples/tests will be set aside for any individuals who have a presumptive positive test result, AND any individuals who have a positive result from any other screening method. Randomly selected samples/tests should also be set aside.

- The samples/tests set aside will be sent to a designated CLIA-certified laboratory for testing.

- Positive results from the CLIA-certified laboratory will be communicated directly to the individual by the CLIA-certified laboratory in a protected manner (not with the facility unless required by law).

Protocols with these elements in place can help facilities prevent COVID-19 transmission by improving the relevance and potential accuracy of screening, without providing results to individuals before confirmation by a CLIA-certified laboratory. Such protocols ensure that individuals are not provided with screening test results in real time, thus preventing a potential diagnosis at the point of screening. Most facilities do not and will not have onsite CLIA-certified laboratories. Therefore, in actual practice, pursuant to FDA policy, individuals will not be receiving their test results as they are screened.

The protocol example provided above requires that other screening methods continue to be used with screening tests, i.e., temperature checks, measurements of oxygen saturation, questions about exposure, etc. The use of electronic thermometers and pulse oximeters is widespread by facilities, even though these devices are (a) not approved, cleared, or otherwise authorized by FDA generally; and (b) not approved, cleared, or otherwise authorized by FDA for the intended use of detecting SARS-CoV-2 in individuals. For many facilities, this causes confusion about FDA policy. Devices that are less ideal than screening tests for preventing the transmission of COVID-19 are permitted by FDA to be used by facilities for screening despite not being reviewed or authorized by the agency. Screening tests cannot be used by facilities without review and authorization by FDA, even though surveillance tests can be. But, just like surveillance tests, no individual results from screening tests used at a facility will be provided to an individual until the test is performed at a CLIA-certified laboratory.

Additionally, the screening tests described in this petition are noninvasive or minimally invasive tests. FDA has precedent for exempting noninvasive devices from agency requirements. For example, in the context of investigational devices, noninvasive diagnostic devices are exempt from requirements under 21 C.F.R. Part 812 if, among other factors, the

device "[d]oes not require an invasive sampling procedure that presents significant risk," "[d]oes not by design or intention introduce energy into a subject," and "[i]s not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure."[20]

The screening tests that can help facilities prevent COVID-19 transmission, and that are the subject of this petition, are noninvasive or minimally invasive, do not require invasive sampling procedures that present significant risk, and do not introduce energy into any subjects. The tests will also be sent to a CLIA-certified laboratory to be performed before any result is provided to an individual. Though screening tests for SARS-CoV-2 are not investigational devices, this analogy demonstrates that FDA has precedent for exempting noninvasive diagnostic devices, including tests, from existing requirements. Here, screening tests do not rise to FDA's categorization of "diagnostic" and the public health emergency created by COVID-19 transmissions is a special circumstance, as are investigations.

The undersigned recognizes that FDA reacted quickly to the public health emergency declared by the Secretary of Health and Human Services, and that the agency is dedicated to making testing for SARS-CoV-2 available. FDA's own FAQ resource states that it is "supportive of testing for COVID-19 that can be performed at home or in other non-laboratory settings, such as offices or schools, provided there is data and science to support consumer safety and test accuracy."[21] The screening tests that are the subject of this petition further this agency goal. The tests would be performed, and the results confirmed, at a CLIA-certified laboratory before any individual results would be reported, thus supporting consumer safety and test accuracy. Moreover, screening tests enable facilities to screen individuals for actual infection of SARS-CoV-2, the virus that causes COVID-19. The data and science behind these tests is more targeted and appropriate for addressing the imminent public health need faced by facilities than the data and science behind electronic thermometers and pulse oximeters, which are only screening for common symptoms of COVID-19 and not serving many facilities' most pressing concerns.

If FDA is concerned that taking the additional administrative action requested in this petition may prompt the use of unauthorized diagnostic tools that go beyond the screening needs of facilities, the undersigned believes FDA could issue guidance, policy, or an additional FAQ that:

[20] 21 C.F.R. § 812.2(c)(3).

[21] *See* FDA, "FAQs on Testing for SARS-CoV-2: Does FDA have validation or other recommendations regarding tests for use at home of other non-laboratory settings, where the collection of a specimen, testing, and interpreting results are all completed outside of a laboratory?" (Updated July 29, 2020), *at* https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general (last visited Oct. 6, 2020).

- Restricts onsite screening tests for facilities to methods that are noninvasive or minimally invasive, and already authorized for home use, including home-use swab kits and home-use spit kits;

- Describes onsite screening tests for use with other accepted screening methods, such as temperature readings, measurements of oxygen saturation, questionnaires, and/or observation of symptoms; and

- Ensures that any communication about results that can be accessed by the facility does not include individual information without further confirmation by a CLIA-certified laboratory.

In sum, screening tests, including molecular in vitro screening tests, for SARS-CoV-2, are noninvasive or minimally invasive testing methods that can improve facilities' ability to prevent COVID-19 transmission. If added to existing screening methods, and used under specified protocol, including that individual results cannot be provided to an individual until confirmed by a CLIA-certified laboratory, screening tests will not diagnose COVID-19 in real time. This use does not raise policy concerns beyond those that have been established for surveillance tests, i.e., results are not provided onsite and individual results are not revealed or reported to individuals unless the test is performed at a CLIA-certified laboratory. Though screening tests are intended to screen individuals, they do not rise to FDA's definition of diagnostic tests for COVID-19, and share characteristics with surveillance tests under both FDA and CMS policies.

Facilities throughout the United States are urgently seeking improved methods by which to screen for and prevent COVID-19 transmission. Our country is also imminently approaching flu season, during which flu symptoms may present as suspected COVID-19 symptoms with many current screening tools. For these reasons, and in the interest of public health, the undersigned requests that FDA take the additional administrative action requested in this petition in a timely manner.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 C.F.R. §§ 25.30 and 25.34.

D. Economic Impact

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by FDA following review of the petition. The undersigned will promptly provide this information if requested.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

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