Contains Nonbinding Recommendations

Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing[1]

This template provides the Food and Drug Administration's (FDA) current recommendations concerning what data and information should be submitted to FDA in support of a pre-Emergency Use Authorization (EUA) submission/EUA request for a molecular or antigen diagnostic test for SARS-CoV-2 used for screening with serial testing.

As outlined in Sections V.A. and V.B. of the FDA guidance document: *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*,[2] FDA recommends certain validation studies be conducted for a SARS-CoV-2 molecular or antigen diagnostic assay. The EUA Templates[3] are intended to help test developers provide validation data and other information to FDA, but alternative approaches can be used. Current templates for molecular and antigen diagnostic tests include recommendations that the developer provide validation data on asymptomatic individuals prior to authorization of a screening claim, including when using a serial testing approach. This template is intended to provide supplemental recommendations for developers of molecular and antigen tests seeking claims for screening with serial testing without studying asymptomatic individuals prior to authorization, including for point-of-care (POC) and at-home tests.

It reflects FDA's current thinking on the topic, and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* means that something is suggested or recommended, but not required. For more information about EUAs in general, please see the FDA guidance document: *Emergency Use Authorization of Medical Products and Related Authorities*.[4]

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[1] This template is part of the "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.

[2] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.

[3] All EUA templates can be found at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#covid19ivdTemplates.

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.

GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow ***[Text]*** should be completed by test developers (sponsor) as applicable to their specific test. Text in **bold** outlines the FDA's additional recommendations for the sponsors' consideration when completing the suggested information in each section.
- This template should be used by developers of molecular or antigen diagnostic tests, for use in serial testing programs as well as tests for serial at-home[5] use by individuals separate from a testing program, including to support authorization for over-the-counter use, intended to detect SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection.
- The information in this template does not reflect complete validation data or information that FDA recommends be included in a pre-EUA submission/EUA request; it supplements the recommendations in the Molecular Diagnostic Template for Commercial Manufacturers, Antigen Template for Test Developers, and Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use, all available for download from FDA's website.[6] Test developers should use one of these referenced templates as their primary template and incorporate information from this supplemental template as applicable.
- A test authorized under an EUA is only authorized for emergency use while the EUA is in effect.
- This is an EUA interactive review template for Pre-EUA submissions/EUA requests. We plan to update the template as appropriate as we learn more about the COVID-19 disease and gain experience with the EUA process for these kinds of tests.

[5] At-home tests are tests labeled for self-testing in any environment outside a clinical laboratory setting, professional healthcare facility, or point-of-care patient care setting operating under a Clinical Laboratory Improvement Amendments (CLIA) certificate. This includes but is not limited to homes, outdoor environments, office environments, schools, vehicles, emergency shelters, and independent living retirement homes. If the test is intended to be used in a clinical laboratory setting, professional healthcare facility, or patient care setting operating under a CLIA certificate and also outside those facilities, it meets this definition.

[6] All EUA templates can be found at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#covid19ivdTemplates.

EXAMPLE TEMPLATE:

[Note: This is intended to provide information to supplement completion of the EUA template most appropriate for your test type. This is not a complete template.]

The supplemental information included in this template is for test developers of molecular or antigen tests interested in offering their test for screening (i.e., testing individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection) with serial testing prior to conducting the asymptomatic validation studies recommended in the corresponding EUA template(s). We note that these recommendations will generally not be applicable to developers with tests for which data has already demonstrated poor performance (e.g., less than 80% PPA) for testing asymptomatic individuals.

A. PROPOSED INTENDED USE

FDA recommends including the following in the requested intended use:

[…*individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection, when tested twice over two (or three) days with at least 24 hours (and no more than 36 hours) between tests.*]

Alternative testing intervals, such as testing every 3 days or testing twice a week (such as Monday/Thursday or Tuesday/Friday), may be considered for molecular or antigen tests intended for use as part of a testing program.

A weekly testing interval may be considered for higher sensitivity molecular tests.

B. CLINICAL PERFORMANCE EVALUATION

FDA recommends following the recommendations for clinical performance evaluation in the appropriate EUA template, except we are including information below for test developers seeking a screening claim (i.e., testing of individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection) with serial testing who have conducted the clinical evaluation with symptomatic patients suspected of COVID-19 infection by their healthcare providers. For a screening claim with serial testing, FDA would generally expect labeling to indicate that testing be done twice over two (or three) days with at least 24 hours (and no more than 36 hours) between tests. Alternative testing

intervals may be considered for molecular or antigen tests intended for use as part of a testing program, as discussed above.

In such circumstances, the developer should generally follow the clinical performance evaluation recommendations in the corresponding molecular or antigen template for validation with symptomatic individuals or individuals otherwise suspected of COVID-19 infection by their healthcare providers. Additionally, for POC and at-home tests, including OTC tests, FDA would consider authorizing tests with a positive percent agreement (PPA) of at least 80% with 70% at the lower bound of the two-sided 95% confidence interval.

As discussed in the Antigen Template for Test Developers, strategies for serial testing with less sensitive tests (i.e., PPA <80%) may be able to be support authorization; however, clinical evaluation in an asymptomatic population would generally be expected prior to authorization of a screening claim, including for OTC use, for such tests.

When FDA authorizes a test for screening with serial testing, but the clinical validation does not include any or the recommended total number of asymptomatic individuals, FDA generally intends to include a condition of authorization in the letter of authorization that the developer conduct a study to establish performance with asymptomatic individuals within a pre-specified timeframe. A study protocol for the post-authorization study, generally including at least 20 positive asymptomatic individuals, should be agreed upon with FDA prior to study initiation. If the post-authorization study is not completed within the agreed upon timeframe or does not demonstrate adequate performance in asymptomatic individuals, FDA would consider taking additional actions as appropriate under section 564 of the FD&C Act, including revoking or revising the authorization to remove any intended use(s) that is not adequately supported.

C. INSTRUCTIONS FOR USE/PROPOSED LABELING/PACKAGE INSERT:

Proposed labeling should clearly identify the population in which the test's performance has been validated, and clearly identify any populations included in the intended use for which the test's performance has not yet been established and will be established during the above referenced post-authorization study.