

*Contains Nonbinding Recommendations*

## **Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing<sup>1</sup>**

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. FDA generally recommends certain validation studies be conducted for a SARS-CoV-2 molecular or antigen diagnostic assays. These recommendations are captured in EUA templates specific to each test type. Test developers should utilize the appropriate template when determining required testing to support each type of test.

As described in the FDA guidance document: *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*,<sup>2</sup> FDA is providing recommendations in this and other EUA templates regarding testing that should be performed to ensure appropriate analytical and clinical validity, including descriptions of appropriate comparators, for different types of tests and indications.

The *EUA Templates*<sup>3</sup> are intended to help test developers provide recommended 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. This template 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*.<sup>4</sup>

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<sup>1</sup> 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>.

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

<sup>3</sup> 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>.

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

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Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to [covid19dx@fda.hhs.gov](mailto:covid19dx@fda.hhs.gov).

FDA recommends that all developers of molecular SARS-CoV-2 tests include the [Molecular EUA Template Cover Sheet](#)<sup>5</sup> when submitting their EUA request to [covid19dx@fda.hhs.gov](mailto:covid19dx@fda.hhs.gov) to help streamline the routing, triage, and review of EUA requests.

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<sup>5</sup> Available at <https://www.fda.gov/media/152768/download>.

## GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow **[Text]** should be completed by the test developer as applicable to their specific test. Text in **bold** outlines the FDA's additional recommendations for the developers' 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. This template also applies to tests for serial at-home<sup>6</sup> use by individuals separate from a testing program, including to support authorization for over-the-counter (OTC) use, intended to detect SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection. **This template is not applicable to tests for which data has already demonstrated poor performance (e.g., less than 80% PPA) for testing asymptomatic individuals.**
- **This is not a complete template.** 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 Template for Molecular Diagnostic Test Developers, Template for Antigen Test Developers, and Template for Test Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Home Use, all available for download from [FDA's website](#).<sup>7</sup> Test developers should use the referenced template most appropriate for their test type 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.
- We plan to update the template as appropriate as we learn more about COVID-19 and gain experience with the EUA process for these kinds of tests.

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<sup>6</sup> 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.

<sup>7</sup> 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>.

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**EXAMPLE TEMPLATE:**

## **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 three days with at least 24 hours and no more than 48 hours between tests.]*

Alternative testing intervals, such as testing twice a week (e.g., 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.

When requesting an intended use that includes both serial testing and single-use testing for different patient populations, FDA recommends including a requested intended use in the following format, with the details adjusted based on your test and validation:

*[The [test name] is a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.]*

*This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 10 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected nasal swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 10 days of symptom onset.*

*This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.]*

## **B. CLINICAL PERFORMANCE EVALUATION**

FDA recommends following the recommendations for clinical performance evaluation in the appropriate EUA template to demonstrate a positive percent agreement (PPA) of at least 80% with 70% at the lower bound of the two-sided 95% confidence interval, in symptomatic patients suspected of COVID-19 infection by their healthcare providers.

When FDA authorizes a test for screening with serial testing, but the clinical validation does not include at least 20 asymptomatic individuals, FDA intends to include a condition of authorization that the developer conduct a study to establish performance with asymptomatic individuals within a pre-specified timeframe. A study protocol for the 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 will 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) not adequately supported.

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

Proposed labeling should indicate that testing be done twice over three days with at least 24 hours and no more than 48 hours between tests. Alternative testing intervals may be considered for molecular or antigen tests intended for use as part of a testing program.

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

The test package should contain adequate testing materials to support your intended use. Therefore, tests intended for serial testing should be packaged to enable serial testing, such as providing at least two tests in a package or, when also intended for single-use testing for symptomatic individuals, include language in the labeling, including on the outer box, such as "If you do not have symptoms of COVID-19, you will need at least two tests per person. You may need to purchase additional tests to perform serial (repeat) testing."

FDA recommends including the following limitations in your Instructions for Use, especially when requesting an intended use that includes both serial testing and single-use testing for different patient populations:

- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.

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- **Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.**

This section applies only to the requirements of the Paperwork Reduction Act of 1995

The burden time for this collection of information is estimated to average 34 to 45 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Operations  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*

**DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS**