

***Contains Nonbinding Recommendations***

**COVER SHEET TEMPLATE**

**Molecular Diagnostic EUA Templates<sup>1</sup>**

This cover sheet template is intended to accompany the EUA templates for molecular diagnostic SARS-CoV-2 tests: [Template for Developers of Molecular Diagnostic Tests](#), [Template for Developers of Home Specimen Collection Devices for Use with Molecular Diagnostic Tests](#), [Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Home Use](#), and [Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing](#).<sup>2</sup>

As described in the FDA guidance document [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#),<sup>3</sup> FDA is providing recommendations in the EUA templates regarding testing that should be performed to ensure analytical and clinical validity, including descriptions of appropriate comparators, for different types of tests. This cover sheet template is intended to help test developers provide these validation data and other information to FDA and streamline the routing, triage, and review of EUA requests by highlighting the characteristics and attributes of each candidate test, but alternative approaches can be used.

FDA recommends that all developers of molecular SARS-CoV-2 tests include this cover sheet when submitting their EUA request to [covid19dx@fda.hhs.gov](mailto:covid19dx@fda.hhs.gov).

**1. *Intended Use Components:***

**Technology (select all that apply for your test):**

- ☐ RT-PCR
- ☐ Real-time RT-PCR
- ☐ LAMP
- ☐ Chemiluminescent
- ☐ MALDI-TOF
- ☐ Sequencing
- ☐ CRISPR
- ☐ TMA
- ☐ Other: ***[Describe technology.]***

<sup>1</sup> The EUA templates are part of the “[Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-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> 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#COVID19vdtTemplates>.

<sup>3</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>

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#### **Specimen types claimed and validated (select all that apply for your test):**

- ☐ Nasopharyngeal (NP) swab
- ☐ Anterior nasal swab
- ☐ Mid-turbinate nasal swab
- ☐ Oropharyngeal (OP) swab specimens
- ☐ Bronchoalveolar lavage (BAL)
- ☐ Sputum
- ☐ Saliva
- ☐ Other: **[Describe specimen type.]**

#### **Single Analyte/Multi-Analyte:**

- ☐ Single Analyte (SARS-CoV-2)  
Number of unique viral targets on the SARS-CoV-2 genome: **[Enter number.]**
- ☐ Multi-Analyte: (If your test is intended for testing multiple respiratory pathogens, please select all analytes detected by your test):
  - ☐ SARS-CoV-2
  - ☐ Flu A
  - ☐ Flu B
  - ☐ RSV
  - ☐ Other: **[Describe other analytes.]**

#### **Intended testing population (select all that apply for your test):**

- ☐ For testing individuals suspected of COVID-19 by their healthcare provider
- ☐ For screening of individuals without symptoms or other reasons to suspect COVID-19 infection.
  - ☐ Serial: **[Describe frequency.]**
  - ☐ Non-serial
- ☐ Other: **[Describe intended testing population.]**

#### **Prescription Use/Non-Prescription Use:**

- ☐ Prescription Use (Rx)
- ☐ Non-Prescription Use

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**Test is intended for use in the following settings (select all that apply for your test):**

- ☐ CLIA-certified labs that meet the requirements for high complexity testing
- ☐ CLIA-certified labs that meet the requirements for moderate complexity testing
- ☐ Point-of-Care/Patient care settings operating under a CLIA Certificate of Waiver
- ☐ Home Collection
- ☐ Home Use
- ☐ Other: ***[Describe intended setting.]***

**Test is for Use with the following Instrument(s) and Extraction Kit(s)/Platform(s):**

Extraction Method and Kit(s)/Platform(s):

- ☐ No extraction needed
- ☐ Extraction is integrated into the test system (e.g., sample to answer system with no user intervention other than loading the sample)
- ☐ Extraction using an automated platform: ***[Fill in extraction kit and platform name(s) and briefly describe the liquid handling solution (e.g., Hamilton OT-2).]***
- ☐ Manual extraction: ***[Fill in extraction kit name(s).]***

Instruments (for example: thermocycler): ***[Fill in instrument name(s).]***

- ☐ Other equipment is needed but not provided: ***[Describe other equipment.]***

**Additional Attributes (select all that apply for your test):**

- ☐ Home specimen collection

For use with the following home specimen collection kit(s): ***[Fill in the name(s) of home specimen collection kit(s) with which you request to be indicated.]***

- ☐ Specimen pooling:
  - ☐ Swab Pooling: ***[Fill in pooling ratio.]***
  - ☐ Media Pooling: ***[Fill in pooling ratio.]***

## ***2. Manufacturing Capacity and Test Throughput:***

**Manufacturing capacity:**

Estimated manufacturing capacity after scale up: ***[Enter manufacturing capacity as a number in units of tests per week.]*** tests per week.

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**Test Throughput (leave blank if not applicable for your technology):**

Length of time for an extraction run: **[Enter length of time as a number.]**

Number of samples per extraction run (e.g., 96 or 384): **[Enter number.]**

Length of time for an amplification run: **[Enter length of time as a number.]**

Number of patient samples per amplification run: **[Enter number.]**

**[Summarize liquid handling capabilities and equipment needed for the extraction and amplification steps.]**

☐ Test includes automated extraction and a liquid handling platform, including for preparation of RT-PCR reaction plates

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