TestingCommons.com

A one-stop reliable source for comprehensive information about COVID-19 tests worldwide. Search all tests in the market and in the pipeline by multiple parameters including test type, technology, regulatory status, country of origin and more.

TestingCommons.com, part of COVID Diagnostics Commons initiative at Arizona State University’s College of Health Solutions
Testing Commons is made possible with support from The Rockefeller Foundation
1. n/a after 10/7/20 when HHS/FDA announced policy to not require authorization for any LDT
2. 19% of tests with approval internationally have been granted EUA by the US FDA
US FDA EUA Test Classifications

- Tests:
  - Molecular Tests (including Appendix A LDTs and Flu panels)
  - Antigen Tests (including Flu panels)
  - Patient Management Tests (IL6)
  - Serology (Antibody) Tests (including cellular immunity)

- Collection Kits
  - Home Collection Kits (Nasal Swabs or Saliva)

- Test Attributes:
  - Test Location (Lab vs. POC vs. Home)
  - Screening (Asymptomatic)
  - Serial Screening
  - Pooling
  - OTC vs Prescription
US FDA Emergency Use Authorizations

**Molecular**
- 88% RTqPCR
- 9% Isothermal
- 3% Sequencing
- 1% CRISPR

**Antigen**
- 88% Lateral Flow
- 8% Chemiluminescence
- 4% other

**Antibody**
- 60% ELISA
- 31% Lateral Flow
- 6% Chemiluminescence

**Other**
- Collection Kits
- Flu/RSV Panels
- Patient Management
Timeline of EUA Issuances and Amendments by Type

- Molecular
- Antigen
- Antibody
- Flu/RSV
- Collection Kit
Profile of US FDA EUA’s

**Sample Type Collected**¹

- Anterior Nasal Swab
- Saliva
- Venous Blood
- Fingerstick Blood
- Nasopharyngeal Swab

**Person to Collect Sample**²

- Health care or Trained Tech
- Self

¹ Only a single Swab type per test counted here, in least to most invasive priority order: Saliva; ANS; lastly NPS/OPS. All PCR tests are sensitive enough to work with nearly all of these swab types: later authorizations specify ANS in addition to other swab methods. ² No specific Healthcare Professional training is required by the EUA (at Laboratory discretion)
## 11 EUA’s for Comprehensive At-Home Tests

<table>
<thead>
<tr>
<th>MOLECULAR TESTS (3)</th>
<th>ANTIGEN TESTS (8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Lucira COVID-19 All-In-One Test Kit</td>
<td>• Abbott BinaxNOW COVID-19 Ag Card Home Test</td>
</tr>
<tr>
<td>• Cue COVID-19 Test for Home and Over The Counter (OTC) Use</td>
<td>• OraSure InteliSwab COVID-19 Rapid Test Rx</td>
</tr>
<tr>
<td>• Lucira CHECK-IT COVID-19 Test Kit</td>
<td>• Quidel QuickVue At-Home OTC COVID-19 Test</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RX TESTS (4)</th>
<th>OTC TESTS (7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Abbott BinaxNOW COVID-19 Ag Card 2 Home Test</td>
<td>• Abbott BinaxNOW COVID-19 Ag Card Home Test</td>
</tr>
<tr>
<td>• Abbott BinaxNOW COVID-19 Antigen Self Test</td>
<td>• Abbott BinaxNOW COVID-19 Ag Card 2 Home Test</td>
</tr>
<tr>
<td>• Ellume COVID-19 Home Test</td>
<td>• OraSure InteliSwab COVID-19 Rapid Test</td>
</tr>
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</tr>
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</tr>
</tbody>
</table>
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.*
## 28 Antigen Tests with EUAs

<table>
<thead>
<tr>
<th>Instrument read</th>
<th>Visual read</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CLIA High/Moderate (Laboratory)</strong></td>
<td><strong>CLIA Waived (Physician Office)</strong></td>
</tr>
<tr>
<td>Celltrion Sampinite</td>
<td>BD Veritor</td>
</tr>
<tr>
<td>DiaSorin LIAISON</td>
<td>BD Veritor + Flu A/B</td>
</tr>
<tr>
<td>Ortho VITROS</td>
<td>Luminostics Clip</td>
</tr>
<tr>
<td>Qorvo Omnia</td>
<td>LumiraDx</td>
</tr>
<tr>
<td>Quanterix Simoa</td>
<td>Quidel Sofia FIA</td>
</tr>
<tr>
<td></td>
<td>Quidel Sofia2+Flu</td>
</tr>
<tr>
<td></td>
<td>Access Bio CareStart</td>
</tr>
<tr>
<td></td>
<td>BinaxNOW Card</td>
</tr>
<tr>
<td></td>
<td>BinaxNOW 2 Card</td>
</tr>
<tr>
<td></td>
<td>Celltrion DiaTrust</td>
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<tr>
<td></td>
<td>InBios SCoV-2</td>
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<tr>
<td></td>
<td>OraSure Inteliswab Pro</td>
</tr>
<tr>
<td></td>
<td>Princeton Status+Flu</td>
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<tr>
<td></td>
<td>Salofa Sienna-Clarity</td>
</tr>
<tr>
<td></td>
<td>Quidel QuickVue</td>
</tr>
</tbody>
</table>

Pandemic Total through 6/30/21
18 EUA’s for Respiratory Panels (Flu, RSV, etc.)

- **Molecular (15)**
  - 67% Lab
  - 33% POC

- **Antigen (3)**
  - 100% POC

Pandemic Total through 6/30/21
Molecular Respiratory Combination Tests (15)
• Abbott Alinity m Resp-4-Plex
• BD for BD MAX system
• BioFire Diagnostics Respiratory Panel 2.1 EZ
• Bio-Rad Reliance
• CDC Flu C2 Multiplex Assay
• Cepheid Xpert Xpress
• GenMark ePlex Respiratory Pathogen Panel 2
• Hologic Aptima
• Luminex NxTAG Respiratory Pathogen Panel + SARS-CoV-2
• NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay
• QIAGEN GmbH QIAstat-Dx Respiratory SARS-CoV-2 Panel
• Quest RC COVID-19+Flu RT-PCR
• Roche cobas
• Roche cobas for use with Liat system
• Thermo Fisher TaqPath

Antigen Respiratory Combination Tests (3)
• BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B
• Princeton BioMeditech Corp. Status COVID-19/Flu
• Quidel Sofia 2 Flu + SARS Antigen FIA

18 EUA’s for Respiratory Panels (Flu, RSV, etc.)
28 EUA’s for Testing of Pooled Samples

- Abbott [Alinity m SARS-CoV-2 assay]
- Amazon DTC [Real-Time RT-PCR Test for Detecting SARS-CoV-2]
- Amazon [Real-Time RT-PCR Test for Detecting SARS-CoV-2]
- Applied BioCode [SARS-CoV-2 Assay]
- Enzo [AMPIPROBE SARS-CoV-2 Test System]
- Hologic [Aptima SARS-CoV-2 assay]
- Hologic [Panther Fusion SARS-CoV-2 Assay]
- Labcorp [COVID-19 RT-PCR Test]
- Labcorp [Pixel Home Collection Kit]
- OPTI SARS-CoV-2 RT-PCR Test
- PerkinElmer [New COVID Nucleic Acid Detection Kit]
- SML GENETREE [Ezplex SARS-CoV-2 G Kit]
- Thermo Fisher TaqPath
- UCSD [RC SARS-CoV-2 Assay]
- Viracor Eurofins [SARS-CoV-2 assay]

Pool size:

- 2 (1 Test): BayCare [SARS-CoV-2 RT PCR Assay]
- 4 (2 Tests)
- 5 (15 Tests)
- 6 (2 Tests)
- 7 (1 Test)
- 8 (2 Tests)
- 12 (2 Tests)
16 EUA’s for Independent Home Specimen Collection Kits

- **Swab (10)**
  - 50% Rx
  - 50% DTC

- **Saliva (6)**
  - 67% Rx
  - 33% DTC

Note: Does not include collection kits included with proprietary assays; only kits separately authorized with independent EUA's
16 EUA’s for Independent Home Specimen Collection Kits

Swab Collection Kits (10)
- binx health At-Home Nasal Swab COVID-19 Sample Collection Kit
- Clinical Enterprises EmpowerDX COVID-19 Home Collection Kit DTC
- Color COVID-19 Self-Swab Collection Kit
- Color COVID-19 Self-Swab Collection Kit DTC
- Color COVID-19 Self-Swab Collection Kit with Saline
- Everlywell COVID-19 Test Home Collection Kit
- Everlywell COVID-19 Test Home Collection Kit DTC
- GetMyDNA COVID-19 Test Home Collection Kit
- Kroger Health COVID-19 Test Home Collection Kit
- RapidRona Self-Collection Kit

Saliva Collection Kits (6)
- DNA GenoTech OMNIgene·ORAL OM-505 and OME-505 (OMNIgene·ORAL) Saliva Collection Device
- DNA GenoTech ORAcollect·RNA OR-100 and ORAcollect·RNA ORE-100 Saliva Collection Device
- Phosphorus Diagnostics LLC Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC
- Spectrum Solutions SDNA-1000 Saliva Collection Device
- WREN Laboratories COVID-19 Saliva Test Collection Kit DTC
- Yale School of Public Health SalivaDirect

Note: Does not include collection kits included with proprietary assays; only kits separately authorized with independent EUA’s
CE-IVD Certified Tests ( Mostly Europe )

Number of Tests

Molecular
- 91% RTqPCR
- 8% Isothermal
- 1% Sequencing

Antigen
- 78% Lateral Flow
- 5% ELISA
- 15% Other

Antibody
- 49% Lateral Flow
- 42% ELISA
- 6% Other

Other
- Collection Kits
- Flu/RSV Panels

Pandemic Total through 6/30/21
Molecular
88% RTqPCR
9% Isothermal
1% Sequencing

Antigen
69% Lateral Flow
27% ELISA
4% Other

Antibody
51% Lateral Flow
47% ELISA
3% Other

Other
- Collection Kits
- Flu/RSV Panels

Pandemic Total through 6/30/21
Tests in Development Worldwide

- Molecular:
  - RTqPCR: 40%
  - Isothermal: 23%
  - CRISPR: 16%
  - Sequencing: 14%

- Antigen:
  - Lateral Flow: 56%
  - ELISA: 18%
  - Breath: 10%
  - Other: 16%

- Antibody:
  - Lateral Flow: 63%
  - ELISA: 25%
  - Other: 12%

- Other:
  - Breath / VOC
  - Mass Spec
  - Raman Spec

Pandemic Total through 6/30/21
Companies with the largest number of EUAs

- **Abbott**: 12 EUAs (4 Molecular, 10 Antibody, 5 Antigen, 3 Antibody)
- **Siemens**: 11 EUAs (3 Molecular, 5 Antibody, 6 Molecular, 1 Antigen, 2 Antibody)
- **Quidel**: 8 EUAs (6 Molecular, 1 Antigen, 2 Antibody)
- **Roche**: 8 EUAs (6 Molecular, 1 Antigen, 2 Antibody)
- **Quest**: 6 EUAs (4 Molecular, 4 Molecular, 1 Antigen, 2 Antibody)
- **BD**: 5 EUAs (1 Molecular, 1 Antigen, 3 Antibody)
- **Color Health**: 5 EUAs (3 Molecular, 2 Antibody)
- **Diasorin**: 5 EUAs (1 Molecular, 1 Antigen, 3 Antibody)
- **Thermo Fisher**: 5 EUAs (3 Molecular, 2 Antibody)

Pandemic Total through 6/30/21
FDA Revoked EUA’s and Other Safety Communications

- **Safety Communications**: FDA posts Medical Device Safety Communications to describe FDA's analysis of a current issue and provide specific regulatory approaches and clinical recommendations for patient management.

- **Letters to Healthcare Providers**: FDA posts the letters it sends to healthcare providers about safety concerns with medical devices used in healthcare facilities.

Pandemic Total through 6/30/21

- Revoked Molecular EUA (7)
- Revoked Antigen EUA (5)
- Revoked Antibody EUA (167)
- Safety Communications (5)
- Letters to Healthcare Providers (9)
Other FDA Safety Communications by Subject

Letters to Health Care Providers
- BD Max
- ThermoFisher
- Roche

Safety Communications
- Curative
- Leccurate
- Lepu Medical
- Innova

Letters to Health Care Providers
- Antibody Testing (2)
- Transport Media
- Self Testing / Nasal Swabs
- Rapid Antigen Tests
- Variants

Pandemic Total through 6/30/21
EUA’s for Management of COVID-19 Patients

IVDs for Management of COVID-19 Patients (3)

- Roche Diagnostics Elecsys IL-6 (June 2020)
- Beckman Coulter, Inc. Access IL-6 (October 2020)
- Siemens Healthcare Diagnostics Inc. ADVIA Centaur IL6 Assay (December 2020)
New EUAs by Technology Q1 2021 (n=41)

Total Q1 2021 New EUA's

- Molecular Tests: 14
- Antigen Tests: 3
- Serology Tests: 10
- Collection Kits: 3

Collection Kits are listed separately as their own category by Testing Commons.
New EUAs by Technology Q2 2021 (n=43)

Total Q2 2021 New EUA’s

Molecular Tests: 13
Antigen Tests: 5
Serology Tests: 8
Collection Kits: 9

- Comprehensive At-Home Tests: 1
- Flu / RSV Combo Tests: 2
- Lab / POC COVID only: 8