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
Insights, trends, and updates from Q3:

• Overall EUA activity from the FDA is down, with
  • 28 new EUA’s in Q3 2021 vs.
  • 45 EUA’s in Q2 and 41 EUA’s in Q1

• Authorizations for pooled testing and serial screening both continued to roll out slowly
  • Neither trend has gained significant momentum despite the April 2021 introduction of a new amendment for Pooling and Screening aimed at further facilitating the authorization of molecular tests for “screening asymptomatic individuals using pooled anterior nasal respiratory specimens in serial testing programs”

• CE-IVD / Research Use Only (RUO) tests continue to show increase in Serology/Antibody tests
TestingCommons.com Pandemic Review

- **FDA EUA**: Molecular, Antigen, Serology, & T-Cell Tests, Patient Management, Combination Respiratory Panels, and Collection Kits
- **LDT**: Schedule IV EUA notifications & Umbrella Molecular EUAs
- **CE-IVD**: EU self-certification
- **Research Use Only**: Tests & Technologies publicly announced to be under development
- **Development**: In US: not for clinical use. Outside US: commercially available
- **FDA Revoked**: Revoked, Rejected, Withdrawn, Warning letter, Fraud (DOJ)

1. Discontinued after 10/7/20 when HHS/FDA announced policy to not require authorization for COVID LDT

Questions: mara.aspinall@asu.edu
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

Number of Tests

Molecular
- 88% RTqPCR
- 8% Isothermal
- 3% Sequencing
- 1% CRISPR

Antigen
- 91% Lateral Flow
- 9% other

Antibody
- 62% ELISA
- 34% Lateral Flow
- 3% Other

Other
- Collection Kits
- Flu/RSV Panels
- Patient Management

Pandemic Total through 9/30/21
## Timeline of EUA Issuances and Amendments by Type

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### Issue Types:
- **Molecular**
- **Antigen**
- **Antibody**
- **Flu/RSV**
- **Collection Kit**
Profile of US FDA EUA’s

Lab Authorized to Analyze Sample

Sample Type Collected

- Swab
- Saliva
- Venous Blood
- Fingerstick Blood

Person to Collect Sample

- Health care or Trained Tech
- Self Collect

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)
# 13 EUA’s for Comprehensive At-Home Tests

### MOLECULAR TESTS (3)
- Lucira COVID-19 All-In-One Test Kit
- Cue COVID-19 Test for Home and Over The Counter (OTC) Use
- Lucira CHECK-IT COVID-19 Test Kit

### ANTIGEN TESTS (10)
- Abbott BinaxNOW COVID-19 Ag Card Home Test
- OraSure InteliSwab COVID-19 Rapid Test Rx
- Quidel QuickVue At-Home OTC COVID-19 Test
- Abbott BinaxNOW COVID-19 Ag Card 2 Home Test
- **Abbott BinaxNOW COVID-19 Antigen Self Test***
- **Access Bio CareStart COVID-19 Antigen Home Test***
- BD Veritor At-Home COVID-19 Test
- Ellume COVID-19 Home Test
- OraSure InteliSwab COVID-19 Rapid Test
- Quidel QuickVue At-Home OTC COVID-19 Test

### RX TESTS (4)
- OraSure InteliSwab COVID-19 Rapid Test Rx
- Quidel QuickVue At-Home OTC COVID-19 Test

### OTC TESTS (9)
- Lucira CHECK-IT COVID-19 Test Kit
- Abbott BinaxNOW COVID-19 Antigen Home Test
- Abbott BinaxNOW COVID-19 Antigen Self Test
- Access Bio CareStart COVID-19 Antigen Home Test
- BD Veritor At-Home COVID-19 Test
- Ellume COVID-19 Home Test
- OraSure InteliSwab COVID-19 Rapid Test
- Quidel QuickVue At-Home OTC COVID-19 Test

*New Q3*

**Pandemic Total through 9/30/21**
EUA’s for Asymptomatic Screening & Serial Screening

Screening (51)
- Collection Kit, 10
- Antigen Home, 1
- Molecular Home, 2
- Molecular POC, 38

Serial Screening (24)
- Antigen Home, 6
- Antigen POC, 10
- Molecular POC, 8

*3 saliva
*4 saliva
*1 saliva

Serial Testing – 2 tests in 24-48 hours

Pandemic Total through 9/30/21
## 35 Antigen Tests with EUAs

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<td>Quidel Sofia FIA</td>
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<tr>
<td>Quanterix Simoa</td>
<td>Quidel Sofia2+Flu</td>
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</table>

- **Access Bio CareStart**
- **ANP Technologies NIDS**
- BinaxNOW Card
- BinaxNOW 2 Card
- Celltrion DiaTrust
- GenBody COVID-19 Ag*
- InBios SCoV-2
- OraSure InteliSwab Pro
- **PHASE Scientific INDICAID**
- Princeton Status+Flu
- Salofa Sienna-Clarity
- Quidel QuickVue

- **Access Bio CareStart**
- BinaxNOW Home Rx
- BinaxNOW Self OTC
- BinaxNOW Telehealth
- OraSure InteliSwab RX
- OraSure InteliSwab OTC
- Quidel QuickVue Rx
- Quidel QuickVue OTC

*New Q3*
22 EUA’s for Respiratory Panels (Flu, RSV, etc.)

- **Molecular (18)**
  - 78% Lab
  - 22% POC

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

- **Collection Kit (1)**
  - 100% Molecular

Pandemic Total through 9/30/21
Molecular Respiratory Combination Tests (18)
- 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 Flu/RSV
- Cepheid Xpert Xpress Flu/RSV Plus
- Exact Science Laboratories COVID-Flu Multiplex
- GenMark ePlex Respiratory Pathogen Panel 2
- Hologic Aptima
- Labcorp SARS-CoV-2 & Influenza A/B Assay
- 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

Molecular Respiratory Combination Collection Kits (1)
- Everlywell COVID-19 & Flu Test Home Collection Kit
32 EUA’s for Testing of Pooled Samples

- CDC [RT-PCR Diagnostic Panel]
- Quest [SARS-CoV-2 Assay]
- Abbott [Alinity m SARS-CoV-2 assay]
- Amazon DTC [RT-PCR Test for Detecting SARS-CoV-2]
- Amazon [Real-Time RT-PCR Test for Detecting SARS-CoV-2]
- Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test
- 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]
- Infinity Biologix TaqPath SARS-CoV-2 Assay
- Labcorp [COVID-19 RT-PCR Test]
- Labcorp [Pixel Home Collection Kit]
- LetsGetChecked Coronavirus (COVID-19) Test
- OPTI SARS-CoV-2 RT-PCR Test
- PerkinElmer [New COVID Nucleic Acid Detection Kit]
- SML GENETREE [Ezplex SARS-CoV-2 G Kit]
- UCSD [RC SARS-CoV-2 Assay]
- Visby Medical COVID-19

- BioFire [COVID-19 Test]
- Cepheid [Xpert Xpress SARS-CoV-2]
- Broad Institute CRSP rPCR Assay (Version 3)
- Viracor Eurofins [SARS-CoV-2 assay]
- Clinical Enterprise SARS-CoV-2 RT-PCR Assay
- Biomeme SARS-CoV-2 Real-Time RT-PCR Test

POOL SIZE

2 (1 Test)
3 (2 Tests)
5 (18 Tests)
6 (2 Tests)
7 (1 Test)
8 (2 Tests)
10 (4 Tests)
12 (2 Tests)

BayCare [SARS-CoV-2 RT PCR Assay]

Poplar [TMA Pooling assay]
19 EUA’s for Independent Home Specimen Collection Kits

Note: Does not include collection kits included with proprietary assays; only kits separately authorized with independent EUA’s

Swab (12)
58% Rx
42% DTC

Saliva (7)
57% Rx
43% DTC

Rx: requires prescription
DTC: direct to consumer

Pandemic Total through 9/30/21
## Swab Collection Kits (12)
- 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
- Everlywell COVID-19 & Flu Test Home Collection Kit
- GetMyDNA COVID-19 Test Home Collection Kit
- Kroger Health COVID-19 Test Home Collection Kit
- Kwokman Diagnostics COVID-19 Home Collection Kit
- RapidRona Self-Collection Kit

## Saliva Collection Kits (7)
- 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
- Yale School of Public Health SalivaDirect DTC

Note: Does not include collection kits included with proprietary assays; only kits separately authorized with independent EUA's

Pandemic Total through 9/30/21
CE-IVD Certified Tests (Mostly Europe)

- Molecular: 90% RTqPCR, 7% Isothermal, 3% Sequencing
- Antigen: 79% Lateral Flow, 4% ELISA, 17% Other
- Antibody: 46% Lateral Flow, 38% ELISA, 16% Other

Other Collection Kits
Flu/RSV Panels

Pandemic Total through 9/30/21
Research Use Only Tests

- **Molecular**
  - 88% RTqPCR
  - 9% Isothermal
  - 2% Other

- **Antigen**
  - 70% Lateral Flow
  - 28% ELISA
  - 2% Other

- **Antibody**
  - 51% Lateral Flow
  - 47% ELISA
  - 2% Other

- **Other**
  - Collection Kits
  - Flu/RSV Panels

Pandemic Total through 9/30/21
Tests in Development Worldwide

- **Molecular**
  - 40% RTqPCR
  - 24% Isothermal
  - 14% CRISPR
  - 14% Sequencing
  - 10% Other

- **Antigen**
  - 59% Lateral Flow
  - 20% ELISA
  - 9% Breath
  - 12% Other

- **Antibody**
  - 63% Lateral Flow
  - 30% ELISA
  - 7% Other

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

Pandemic Total through 9/30/21
Companies with the largest number of EUAs

- **Abbott**: 12 tests (4 Molecular, 5 Antigen, 3 Antibody)
- **Siemens**: 12 tests (1 Molecular, 10 Antibody, 1 Pt Mgmt)
- **Roche**: 10 tests (6 Molecular, 2 Antibody, 1 Pt Mgmt)
- **Danaher***: 9 tests (5 Molecular, 3 Antibody)
- **Quidel**: 8 tests (3 Molecular, 3 Antibody)
- **BD**: 8 tests (6 Molecular, 1 Pt Mgmt)
- **Thermo Fisher**: 7 tests (5 Molecular, 1 Antibody)
- **Quest**: 6 tests (6 Molecular, 3 Antibody)
- **Color Health**: 5 tests (5 Molecular, 3 Antibody)
- **Diasorin**: 5 tests (1 Molecular, 1 Pt Mgmt)

*Beckman Coulter & Cepheid

Number of Tests

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Pandemic Total through 9/30/21
FDA Revoked EUA’s & 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 health care providers about safety concerns with medical devices used in health care facilities.

Revoked EUA categories:
- Revoked Antibody EUA (168)
- Revoked Molecular EUA (9)
- Revoked Antigen EUA (5)
- Safety Communications (8)
- Letters to Healthcare Providers (15)
Other FDA Safety Communications by Subject

- **Warning Letters to Ancillary Companies**
  - Blue Willow Biologics
  - Invisi Smart Technologies
  - Jordan’s Crossing Herbal Connections
  - Kaleido Biosciences, Inc.
  - Mahita, LLC dba PushMyCart
  - Rxmedcart.com
  - Shanghai Dasheng

- **Safety Communications**
  - Abbott
  - Curative
  - Innova
  - Leccurate
  - Lepu Medical
  - Quidel

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

- **Safety Communications**
  - Antibody Testing (2)
  - Transport Media
  - Self Testing / Nasal Swabs
  - Rapid Antigen Tests
  - Variants

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

**Pandemic Total through 9/30/21**
EUA’s for Management of COVID-19 Patients

IVDs for Management of COVID-19 Patients (4)

- 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)
- BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) (August 2021)
New EUAs by Technology Q3 2021 (n=28)

Total Q3 2021 New EUA's

- Molecular Tests: 10
- Antigen Tests: 5
- Serology Tests: 5
- Collection Kits: 3

- Comprehensive At-Home Tests
- Flu / RSV Combo Tests
- Lab / POC COVID only
New EUAs by Technology Q2 2021 (n=45)

Total Q2 2021 New EUA's

- Molecular Tests: 15
- Antigen Tests: 6
- Serology Tests: 8
- Collection Kits: 9

- Comprehensive At-Home Tests
- Flu / RSV Combo Tests
- Lab / POC COVID only
New EUAs by Technology Q1 2021 (n=41)

Total Q1 2021 New EUA’s

- Molecular Tests: 1 (Comprehensive At-Home Tests), 6 (Flu / RSV Combo Tests), 14 (Lab / POC COVID only)
- Antigen Tests: 3 (Comprehensive At-Home Tests), 1 (Flu / RSV Combo Tests), 3 (Lab / POC COVID only)
- Serology Tests: 10 (Lab / POC COVID only)
- Collection Kits: 3 (Lab / POC COVID only)

Collection Kits are listed separately as their own category by Testing Commons.
Acknowledgements

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• ASU Decision Theater
  • The team’s work is critical to the success of all of our systems

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  • For continued commitment to education