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COVID-19 Point-of-Care Testing

The chart below reviews pertinent information about available point-of-care (POC) COVID-19 tests available in the U.S. Information in each row of the chart is from the device product labeling unless otherwise specified. Proceed to the end of the chart for information about personal protective equipment, obtaining specimens, patient follow up, and billing for COVID-19 POC tests. See our chart, *COVID-19 Testing FAQs*, for more on who should be tested and interpreting and reporting test results. Our chart, *Point-of-Care Testing in Pharmacies*, includes a listing of other available POC tests (e.g., flu, strep, etc) and guidance on how to start a POC testing service in your pharmacy.

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
Molecular tests for rapid detection of COVID-19			
Cue COVID-19[4] Results: ~25 minutes	**Storage**: • 59°F to 86°F (15°C to 30°C) **Operation**: • 59°F to 86°F (15°C to 30°C) • Has not been tested at high temperatures or in humidity	• nasal swab	• Avoid opening foil pouch more than 30 minutes before beginning a test. • Swab both nostrils with the same swab. • Must insert swab into testing cartridge within 5 minutes of sample collection.

ID Now COVID-19[5]
 	
Results: ~15 minutes
	Storage:
	• 36°F to 86°F (2°C to 30°C)
	
	Operation (if refrigerated, bring kit to room temp prior to use):
	• 59°F to 86°F [15°C to 30°C]
		• nasopharyngeal swab
		• nasal swab
		• throat swab
			• Avoid opening foil pouch until just before use.
			• Swab both nostrils with the same swab.
			• If test is not run immediately after collection, specimens can be stored:
			  • at room temp (59°F to 86°F [15°C to 30°C]) for ≤2 hours.
			  • in the refrigerator (36°F to 46°F [2°C to 8°C]) for ≤24 hours. Bring samples to room temperature before testing.
			• **Avoid use of transport media solution** if storing specimens before testing due to risk of false-negative results.

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POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
Molecular tests for rapid detection of COVID-19, continued			

Accula SARS-CoV-2[6]
 	
Results: ~30 minutes
	Storage and Operation:
	• 59°F to 86°F (15°C to 30°C)
		• nasal swab	• Avoid opening foil pouch more than 30 minutes before beginning a test.
			• Swab both nostrils with the same swab.
			• If test is not run immediately after collection:
			  • **unprepared specimens** can be stored:
			  • at room temp (59°F to 86°F [15°C to 30°C]) for ≤2 hours.
			  • in the refrigerator (36°F to 46°F [2°C to 8°C]) for ≤24 hours.
			  • **prepared specimens** (after adding buffer) can be stored:[a]
			  • at room temperature for ≤24 hours.
			  • refrigerated for ≤72 hours.
			  • frozen at -4°F (-20°C) for ≤1 week.
			• **Avoid use of transport media solution** if storing specimens before testing due to risk of invalidating test results.

Xpert Xpress SARS-CoV-2[7]
 	
Results:[8] ~45 minutes
	Storage:
	• 36°F to 82°F (2°C to 28°C)
	Operation (if refrigerated, bring kit to room temp prior to use):
	• 59°F to 86°F (15°C to 30°C) with 20% to 80% relative humidity[9]
		• nasopharyngeal swab
		• nasal swab
		• mid-turbinate swab
			• If test is not run immediately after collection specimens in viral transport medium or saline can be stored:
			  • at room temp (59°F to 86°F [15°C to 30°C]) for ≤8 hours.
			  • refrigerated (36°F to 46°F [2°C to 8°C]) for ≤7 days.

COVID-19 All-in-One Test Kit[23] Results: ~30 minutes	**Storage**: • 59°F to 86°F (15°C to 30°C) **Operation**: • 41°F to 113°F (5°C to 45°C) with 5% to 95% humidity	• nasal swab	• Avoid opening foil pouch until just before use. • Swab both nostrils with the same swab. • Run test immediately after collection. • Approved (requires a prescription) for at-home self-collection and self-testing for patients 14 years and older.

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
Molecular tests for rapid detection of COVID-19 and Influenza A/B			

Cobas SARS-CoV-2 & Influenza A/B[15]
 	
Results: ~20 minutes
	Storage:
	• 36°F to 46°F (2°C to 8°C)
	
	Operation (bring kit to room temp prior to use):
	• 59°F to 86°F (15°C to 30°C)
		• nasopharyngeal swab
		• nasal swab
			• Swab both nostrils with the same swab.
			• If test is not run immediately after collection specimens in viral transport medium can be stored:
			  • at room temp (59°F to 86°F [15°C to 30°C]) ≤4 hours.
			  • refrigerated (36°F to 46°F [2°C to 8°C]) ≤72 hours.

BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)[17]
 	
Results: ~45 minutes
	Storage and Operation:
	• 59°F to 77°F (15°C to 25°C)
		• nasopharyngeal swab	• Avoid opening pouch until just before use.
			• If test is not run immediately after collection, specimens in up to 3 mL of transport medium can be stored:
			  • at room temp 59°F to 77°F (15°C to 25°C) for ≤4 hours
			  • refrigerated (36°F to 46°F [2°C to 8°C]) for ≤3 days. Bring refrigerated specimens to room temperature before testing.

Xpert Xpress SARS-CoV-2/Flu/RSV[18]
 	
Results: ~30 minutes[19]
	Storage:
	• 36°F to 82°F (2°C to 28°C)
	
	Operation (if refrigerated, bring kit to room temp prior to use):
	• 59°F to 86°F (15°C to 30°C) with 20% to 80% relative humidity
		• nasopharyngeal swab
		• nasal swab
			• When collecting nasal swab specimens, swab both nostrils with the same swab. (Only one nostril is used for nasopharyngeal specimen collection.)
			• If test is not run immediately after collection, specimens in 3 mL of viral transport medium can be stored:
			  • at room temp 59°F to 86°F (15°C to 30°C) for ≤24 hours
			  • refrigerated (36°F to 46°F [2°C to 8°C]) for ≤7 days. Bring refrigerated specimens to room temperature before testing.

Antigen tests for rapid detection of COVID-19 (Negative results do NOT rule out COVID-19. If necessary, confirm with a molecular test.)			
BinaxNow COVID-19 Ag Card[10] Results: ~15 minutes	**Storage**: • 36°F to 86°F (2°C to 30°C) **Operation** (if refrigerated, bring kit to room temp prior to use): • 59°F to 86°F (15°C to 30°C)	• nasal swab	• Avoid opening foil pouch until just before use. • Swab both nostrils with the same swab. • Conduct test within one hour of specimen collection. False negative results may occur if specimens are tested past one hour of collection. • Avoid storing specimens in viral transport media.

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
Antigen tests for rapid detection of COVID-19, continued			

LumiraDx SARS-CoV-2 Ag Test[14]
 	
Results: ~15 minutes
	Storage:
	• 36°F to 86°F (2°C to 30°C)
	
	Operation (if refrigerated, bring kit to room temp prior to use):
	• 59°F to 86°F (15°C to 30°C)
		• nasal swab	• Avoid opening foil pouch until just before use.
			• Swab both nostrils with the same swab.
			• If test is not run immediately after collection, specimens can be stored:
			  • at room temperature (59°F to 86°F [15°C to 30°C]) for ≤5 hours.
			  • frozen (-112°F [-80°C]) ≤5 days. Bring frozen samples to room temperature before testing.

BD Veritor System for Rapid Detection of SARS-CoV-2[11] Results: ~15 minutes	**Storage**: • 36°F to 86°F (2°C to 30°C) **Operation (**if refrigerated, bring kit to room temp prior to use): • 59°F to 86°F (15°C to 30°C)	• nasal swab	• Avoid opening foil pouch until just before use. • Swab both nostrils with the same swab. • After processing the swab in the extraction reagent, tests must be run within 30 minutes.
Sofia 2 SARS Antigen FIA[12] Results: ~15 minutes	**Storage and Operation**: • 59°F to 86°F (15°C to 30°C)	• nasopharyngeal swab • nasal swab	• Avoid opening foil pouch until just before use. • Collect sample using one nostril, preferably the nostril with the most secretion. • If test is not run immediately after collection, **unprepared specimens** can be stored: • at room temperature (59°F to 86°F [15° to 30°C]) or refrigerated (36°F to 46°F [2°C to 8°C]) ≤48 hours. Bring refrigerated samples to room temperature before testing. • **Prepared specimens** can be stored out of direct sunlight, at room temperature, for ≤6 hours before testing. • Not recommended for use with viral transport media.[13]

CareStart COVID-19 Antigen[22]
 	
Results: ~10 minutes
	Storage:
	• 34°F to 86°F (1°C to 30°C)
	
	Operation (if refrigerated, bring kit to room temp prior to use):
	• 59°F to 86°F (15°C to 30°C)
		• nasopharyngeal swab	• Avoid opening foil pouch until just before use.
			• Collect sample using one nostril.
			• Avoid reading results <10 minutes or >15 minutes after starting the test.
			• If test is not run immediately after collection, specimens can be stored in extraction buffer:
			  • at room temperature (59°F to 86°F [15°C to 30°C]) for ≤4 hours.
			  • frozen (-112°F [-80°C]) ≤5 days. Bring frozen samples to room temperature before testing.

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
Serology (antibody) tests for rapid detection of an immune response to a recent exposure to SARS-CoV-2. (Should generally NOT be used to diagnose COVID-19. **Positive results do not mean patients are immune or protected from reinfection.**)			
Assure/FaStep COVID-19 IgG/IgM Rapid Test[16] Results: ~15 minutes	**Storage**: • 36°F to 86°F (2°C to 30°C) **Operation** (if refrigerated, bring kit to room temp prior to use): • 59°F to 86°F (15°C to 30°C)	• fingerstick	• Qualitative (yes/no), not quantitative (number of antibodies) results. • Avoid opening foil pouch until just before use. • Avoid reading results <15 minutes or >30 minutes after adding the buffer. • If test is not run immediately after collection, specimens can be stored: • refrigerated (36°F to 46°F [2°C to 8°C]) for ≤7 days. Bring refrigerated specimens to room temperature before testing. • Confirm positive results with a different IgG or IgM assay, due to the risk of false positive results from cross-reactivity with other antibodies.

a. Based on viability data from testing similar viruses in the *Accula SARS-CoV-2* test buffer.

--Continue to the Next Page for Tips for COVID-19 POC Testing--

Tips for COVID-19 POC Testing

- Molecular and antigen tests detect **active COVID-19 infection**. Serology (antibody) tests detect an immune response to a previous exposure to SARS-CoV-2.[1]
- In the U.S., pharmacies can use the following CPT code for POC COVID-19 testing: U0002.[2] Prescriber offices can refer to the American Medical Association's most current guidance on COVID-19 coding and guidance at https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-coding-and-guidance. For locations looking to obtain a CLIA wavier, the Centers for Medicare & Medicaid (CMS) released a quick-start guide to streamline the CLIA-waiver certification process for labs conducting testing for COVID-19.[21] The quick-start guide can be found at https://www.cms.gov/files/document/laboratory-quick-start-guide-cms-clia-certification.pdf.
- **Use proper PPE**. Ensure access, necessary training, fit testing (if using N95 respirators), and adherence to guidance (e.g., CDC [https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html]) for PPE.
- Know **how to obtain specimens** for POC testing.
  - See product information for how to collect specimens.
  - A video demonstrating nasopharyngeal specimen collection is available at: https://www.nejm.org/doi/full/10.1056/NEJMvcm2010260?query=RP.
- **Use an appropriate space to collect specimens**. For example, use an isolated space outside of the pharmacy to collect specimens (e.g., the parking lot [drive thru windows may not ensure proper protection, especially if not using supervised self-collection methods]).[3]
- Follow policies and procedures for reporting positive and negative test results to patients, and local and state health departments.
- For all patients with symptoms, regardless of test results, discuss symptom management (e.g., fluids, antipyretic for fever).
- Patients with positive COVID-19 test should be given **instructions on isolation procedures** (https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html) and if tested in a pharmacy, referred to their prescriber for further evaluation and management.
- Have a system to **follow-up with patients** to ensure referrals are complete, check that symptoms are improving, or assess med tolerability.

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