

June 2021 ~ Resource #370603

## COVID-19 Point-of-Care Testing

This chart reviews pertinent information about point-of-care (POC) and home COVID-19 tests available in the U.S. Information within the chart is from the device product labeling unless otherwise noted. At the end of the chart, find 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 who should be tested and interpreting test results. Our chart, *Point-of-Care Testing in Pharmacies*, includes other available POC tests (e.g., flu, strep, etc) and tips to start a POC testing service in your pharmacy.

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
<b>Molecular tests for rapid detection of COVID-19 authorized for HOME use</b>			
Instruct patients to follow test instructions, share ALL test results with their prescriber, and dispose of the testing materials per instructions.			
<p><i>Cue COVID-19 Test for Home and Over The Counter (OTC) Use</i><sup>38</sup></p> <p>Results:<sup>45</sup> ~20 minutes</p> <p>Cost: Approved but not available at time of publication</p>	<p><b>Storage and Operation:</b></p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> <li>• self-collection (adults)</li> <li>• adult-assisted collection (children ≥2 years old)</li> </ul>	<ul style="list-style-type: none"> <li>• Authorized OTC for use in people ≥2 years old with or without COVID-19 symptoms.</li> <li>• Smartphone, Cue Health mobile app, and Cue Health Monitoring System (sold separately) required PRIOR to use.</li> <li>• Email support@cuehealth.com or call 833-283-8378 to purchase the Cue Health Monitoring System.</li> <li>• For detailed instructions visit <a href="https://www.cuehealth.com/documentation/home-otc/Cue_COVID-19_OTC_Test_Instructions_For_Use_(IFU).pdf">https://www.cuehealth.com/documentation/home-otc/Cue_COVID-19_OTC_Test_Instructions_For_Use_(IFU).pdf</a>.</li> </ul>
<p><i>Lucira CHECK IT COVID-19 Test Kit (OTC)</i><sup>36</sup></p> <p>Results: ~30 minutes</p> <p>Cost:<sup>37</sup> ~\$55</p>	<p><b>Storage and Operation:</b></p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> <li>• self-collection (≥14 years old)</li> <li>• adult-assisted collection (children 2 to 13 years old)</li> </ul>	<ul style="list-style-type: none"> <li>• For use in people ≥2 years old with or without COVID-19 symptoms.</li> <li>• Instruct patients to use the LUCI portal to have verified test results sent to their phone and transmitted to public health agencies. To start this process patients, need to text “LUCI” to 44544.</li> <li>• For detailed instructions visit <a href="https://checkit.lucirahealth.com/">https://checkit.lucirahealth.com/</a>.</li> </ul>
<p><i>Lucira COVID-19 All-in-One Test Kit (Rx)</i><sup>23</sup></p> <p>Results: ~30 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul> <p><b>Operation:</b></p> <ul style="list-style-type: none"> <li>• 41°F to 113°F (5°C to 45°C) with 5% to 95% humidity</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> <li>• self-collection (≥14 years old)</li> </ul>	<ul style="list-style-type: none"> <li>• Authorized for HOME testing (<b>WITH a prescription</b>) for people ≥14 years old who are suspected to have COVID-19 by their prescriber.</li> <li>• For detailed instructions visit <a href="https://shop.lucirahealth.com/">https://shop.lucirahealth.com/</a>.</li> </ul>

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
<b>Molecular tests for rapid detection of COVID-19 authorized for POC use</b>			
<p><i>Accula SARS-CoV-2</i><sup>6</sup></p> <p>Results: ~30 minutes</p>	<p><b>Storage and Operation:</b></p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> <li>• mid-turbinate swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open pouch &gt;30 minutes before beginning a test.</li> <li>• Swab both nostrils with the same swab.</li> <li>• Add buffer to sample immediately after collection.               <ul style="list-style-type: none"> <li>• If test is not run immediately after collection (and adding buffer), specimens can be stored:                   <ul style="list-style-type: none"> <li>• at room temp for up to two hours.</li> <li>• refrigerated for up to 24 hours.</li> </ul> </li> </ul> </li> <li>• <b>Avoid use of transport media solution</b> if storing specimens before testing due to risk of invalidating test results.</li> </ul>
<p><i>Cue COVID-19</i><sup>4</sup></p> <p>Results: ~20 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul> <p><b>Operation:</b></p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> <li>• Has not been tested at higher or lower temperatures or in high humidity.</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open pouch &gt;30 minutes before beginning a test.</li> <li>• Swab both nostrils with the same swab.</li> <li>• Must insert swab into testing cartridge within five minutes of sample collection.</li> <li>• Alternatively, swabs can be used to test previously collected, properly stored nasal specimens in viral transport medium. See product information for these instructions.</li> </ul>
<p><i>ID Now COVID-19</i><sup>5</sup></p> <p>Results: ~15 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <p><b>Operation</b> (if refrigerated, bring to room temp for use):</p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> <li>• nasal swab</li> <li>• throat swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open pouch until just before use.</li> <li>• Swab both nostrils with the same swab.</li> <li>• If test is not run immediately after collection, specimens can be stored at room temp for ≤1 hour.</li> <li>• <b>Avoid use of transport media solution</b> if storing specimens before testing due to risk of false-negative results.</li> </ul>
<p><i>Lucira COVID-19 All-in-One Test Kit</i><sup>23</sup></p> <p>Results: ~30 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul> <p><b>Operation:</b></p> <ul style="list-style-type: none"> <li>• 41°F to 113°F (5°C to 45°C) with 5% to 95% humidity</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Approved for POC testing without age restrictions.</li> <li>• Do NOT open pouch until just before use.</li> <li>• Swab both nostrils with the same swab.</li> <li>• Run test immediately after collection.</li> </ul>

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
<b>Molecular tests for rapid detection of COVID-19 authorized for POC use, continued</b>			
<p><i>Visby Medical COVID-19 Point of Care Test</i><sup>35</sup></p> <p>Results: ~30 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <p><b>Operation:</b></p> <ul style="list-style-type: none"> <li>• 66°F to 82°F (19°C to 28°C) with 30% to 80% humidity</li> </ul>	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> <li>• nasal swab</li> <li>• mid-turbinate swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open pouch until just before use.</li> <li>• When collecting nasal or mid-turbinate swab specimens, swab both nostrils with the same swab. (Only one nostril for nasopharyngeal specimens.)</li> <li>• Add buffer to sample immediately after collection.</li> <li>• If test is not run immediately after collection (and adding buffer), specimens can be stored:               <ul style="list-style-type: none"> <li>• at room temp for up to 45 minutes.</li> <li>• refrigerated for up to 24 hours.</li> </ul> </li> </ul>
<p><i>Xpert Omni SARS-CoV-2</i><sup>39</sup></p> <p>Results: Not available at time of publication</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 36°F to 82°F (2°C to 28°C)</li> </ul> <p><b>Operation</b> (if refrigerated, bring to room temp for use):</p> <ul style="list-style-type: none"> <li>• <b>recommended:</b> 59°F to 86°F (15°C to 30°C) with 20% to 80% relative humidity</li> <li>• <b>allowable:</b> 59°F to 104°F (15°C to 40°C) with 16% to 90% relative humidity</li> </ul>	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> <li>• nasal swab</li> <li>• mid-turbinate swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open cartridge lid until just before use.</li> <li>• When collecting nasal swab specimens, swab both nostrils with the same swab. (Only one nostril for mid-turbinate and nasopharyngeal specimens.)</li> <li>• Run test within 30 minutes of adding the sample to the cartridge.</li> <li>• If test is not run immediately after collection, specimens in transport medium, saline, or eNAT transport medium can be stored:               <ul style="list-style-type: none"> <li>• at room temp for up to eight hours.</li> <li>• refrigerated for up to seven days.</li> </ul> </li> </ul>
<p><i>Xpert Xpress SARS-CoV-2</i><sup>7</sup></p> <p>Results:<sup>8</sup> ~45 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 36°F to 82°F (2°C to 28°C)</li> </ul> <p><b>Operation</b> (if refrigerated, bring to room temp for use): 59°F to 86°F (15°C to 30°C) with 20% to 80% relative humidity<sup>9</sup></p>	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> <li>• nasal swab</li> <li>• mid-turbinate swab</li> <li>• oropharyngeal</li> </ul>	<ul style="list-style-type: none"> <li>• If test is not run immediately after collection, specimens in viral transport medium or saline can be stored:               <ul style="list-style-type: none"> <li>• at room temp for up to eight hours.</li> <li>• refrigerated for up to seven days.</li> </ul> </li> <li>• Run test within 30 minutes of adding the sample to the cartridge.</li> <li>• Performance has only been established with nasopharyngeal swabs, but nasal, mid-turbinate, and oropharyngeal swabs are considered acceptable specimens.</li> </ul>

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
<b>Molecular tests for rapid detection of COVID-19 and Influenza A/B authorized for POC use</b>			
<i>BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)</i> <sup>17</sup>  Results: ~45 minutes	<b>Storage and Operation:</b> <ul style="list-style-type: none"> <li>• 59°F to 77°F (15°C to 25°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open pouch &gt;30 minutes before beginning a test.</li> <li>• If test is not run immediately after collection, specimens in up to 3 mL of transport medium or saline can be stored:               <ul style="list-style-type: none"> <li>• at room temp for up to four hours.</li> <li>• refrigerated for up to three days. Bring refrigerated specimens to room temp before testing.</li> </ul> </li> </ul>
<i>Cobas SARS-CoV-2 &amp; Influenza A/B</i> <sup>15</sup>  Results: ~20 minutes	<b>Storage:</b> <ul style="list-style-type: none"> <li>• 36°F to 46°F (2°C to 8°C)</li> </ul> <b>Operation</b> (bring to room temp for use): <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Swab both nostrils with the same swab.</li> <li>• If test is not run immediately after collection, specimens in viral transport medium or normal saline can be stored:               <ul style="list-style-type: none"> <li>• at room temp for up to four hours.</li> <li>• refrigerated for up to 72 hours.</li> </ul> </li> <li>• Once specimens have been transferred to the assay tube, they may be stored at room temp for up to four hours.</li> </ul>
<i>Xpert Xpress SARS-CoV-2/Flu/RSV</i> <sup>18</sup>  Results: ~30 minutes <sup>19</sup>	<b>Storage:</b> <ul style="list-style-type: none"> <li>• 36°F to 82°F (2°C to 28°C)</li> </ul> <b>Operation</b> (if refrigerated, bring to room temp for use): <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C) with 20% to 80% relative humidity</li> </ul>	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• When collecting nasal swab specimens, swab both nostrils with the same swab. (Only one nostril for nasopharyngeal specimens.)</li> <li>• If test is not run immediately after collection, specimens in 3 mL of viral transport medium or saline can be stored:               <ul style="list-style-type: none"> <li>• at room temp for up to 24 hours (in viral transport medium) or 48 hours (in saline).</li> <li>• refrigerated for up to seven days (in viral transport medium or saline). Bring refrigerated specimens to room temp before testing.</li> </ul> </li> </ul>
<b>Antigen tests for rapid detection of COVID-19 authorized for HOME use</b> (Negative results do NOT rule out COVID-19, especially in patients with symptoms. If necessary, confirm with a molecular test.) Instruct patients to follow test instructions, share ALL test results with their prescriber, and dispose of the testing materials per instructions.			
<i>BinaxNow COVID-19 Ag Card Home Test (Rx)</i> <sup>51</sup>  Results: ~15 minutes	<b>Storage:</b> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <b>Operation</b> (if refrigerated, bring to room temp for use): <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> <li>• self-collection (≥15 years old)</li> <li>• Adult-assisted collection (children 4 to 14 years old)</li> </ul>	<ul style="list-style-type: none"> <li>• For people ≥4 years old within seven days of COVID-19 symptom onset.</li> <li>• Performed with certified guides to supervise testing during a video call. Results can be sent to the patient through the NAVICA app. Prescribers report results to public health authorities.</li> <li>• For detailed instructions visit <a href="https://www.globalpointofcare.abbott/en/product-details/binaxnow-covid-19-home-test-us.html">https://www.globalpointofcare.abbott/en/product-details/binaxnow-covid-19-home-test-us.html</a>.</li> </ul>

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
<b>Antigen tests for rapid detection of COVID-19 authorized for HOME use, continued</b> (Negative results do NOT rule out COVID-19, especially in patients with symptoms. If necessary, confirm with a molecular test.) Instruct patients to follow test instructions, share ALL test results with their prescriber, and dispose of the testing materials per instructions.			
<i>BinaxNow Ag Card 2 Home Test (OTC)</i> <sup>52,*</sup> Results: ~15 minutes *Authorized, but not available at time of publication	<b>Storage:</b> • 36°F to 86°F (2°C to 30°C)  <b>Operation</b> (if refrigerated, bring to room temp for use): • 59°F to 86°F (15°C to 30°C)	<ul style="list-style-type: none"> <li>• nasal swab</li> <li>• self-collection (≥15 years old)</li> <li>• Adult-assisted collection (children 2 to 14 years old)</li> </ul>	<ul style="list-style-type: none"> <li>• For people ≥2 years old with or without symptoms indicated for serial testing twice within three days, ensuring at least 36 hours between tests.</li> <li>• Only to be performed with a telehealth proctor. Results are sent to the patient through email and the NAVICA app.</li> <li>• Patients are to report their results to their prescriber in order to have results sent to the public health authorities.</li> </ul>
<i>BinaxNow COVID-19 Antigen Self Test (OTC)</i> <sup>27</sup> Results: ~15 minutes Cost: <sup>44</sup> ~\$24 (includes two tests)	<b>Storage:</b> • 36°F to 86°F (2°C to 30°C)  <b>Operation</b> (if refrigerated, bring to room temp for use): • 59°F to 86°F (15°C to 30°C)	<ul style="list-style-type: none"> <li>• nasal swab</li> <li>• self-collection (≥15 years old)</li> <li>• Adult-assisted collection (children 2 to 14 years old)</li> </ul>	<ul style="list-style-type: none"> <li>• For people ≥2 years old with or without symptoms indicated for serial testing twice within three days, ensuring at least 36 hours between tests.</li> <li>• Each kit contains two tests and is indicated for serial self-testing twice within three days, ensuring at least 36 hours between tests.</li> <li>• Patients are to report their results to their prescriber in order to have results sent to the public health authorities.</li> <li>• For detailed instructions visit <a href="https://www.globalpointofcare.abbott/en/product-details/binaxnow-covid-19-antigen-self-test-us.html">https://www.globalpointofcare.abbott/en/product-details/binaxnow-covid-19-antigen-self-test-us.html</a>.</li> </ul>
<i>Ellume COVID-19 Home Test (OTC)</i> <sup>28</sup> Results: ~15 minutes Cost: <sup>48</sup> ~\$40	<b>Storage:</b> • 36°F to 86°F (2°C to 30°C)  <b>Operation</b> (if refrigerated, bring to room temp for use): • 59°F to 77°F (15°C to 25°C)	<ul style="list-style-type: none"> <li>• mid-turbinate swab</li> <li>• self-collection (≥16 years old)</li> <li>• Adult-assisted collection (children 2 to 15 years old)</li> </ul>	<ul style="list-style-type: none"> <li>• For people ≥2 years with or without symptoms.<sup>25,28,30</sup> Includes an adapter to shorten swab for use in children between 2 and 12 years.</li> <li>• Smartphone and smartphone app required PRIOR to use.</li> <li>• Results are automatically sent to smartphone app and public health authorities via secure, HIPAA-compliant cloud connection. Results can also be emailed.<sup>25,28</sup></li> <li>• Test should not be used in people prone to nosebleeds or with a history of facial or head injury or surgery in the last six months.</li> <li>• For detailed instructions visit <a href="https://www.ellumecovidtest.com/">https://www.ellumecovidtest.com/</a>.</li> </ul>

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
<b>Antigen tests for rapid detection of COVID-19 authorized for HOME use, continued</b> (Negative results do NOT rule out COVID-19, especially in patients with symptoms. If necessary, confirm with a molecular test.) Instruct patients to follow test instructions, share ALL test results with their prescriber, and dispose of the testing materials per instructions.			
<i>QuickVue At-Home OTC COVID-19 Test</i> <sup>40</sup>  Results: <sup>47</sup> ~10 minutes  Cost: <sup>46</sup> ~\$30 (includes two tests)	<b>Storage and Operation:</b> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> <li>• self-collection (≥14 years old)</li> <li>• Adult-assisted collection (children 2 to 13 years old)</li> </ul>	<ul style="list-style-type: none"> <li>• For people ≥2 years old with or without symptoms.</li> <li>• Each kit contains two tests and is indicated for serial self-testing twice within three days, ensuring 24 to 36 hours between tests.</li> <li>• Patients are to report their results to their prescriber in order to have results sent to the public health authorities.</li> <li>• For detailed instructions visit <a href="https://quickvueathome.com/">https://quickvueathome.com/</a>.</li> </ul>
<i>QuickVue At-Home COVID-19 Test (Rx)</i> <sup>54</sup>  Results: ~10 minutes	<b>Storage and Operation:</b> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> <li>• self-collection (≥14 years old)</li> <li>• Adult-assisted collection (children 8 to 13 years old)</li> </ul>	<ul style="list-style-type: none"> <li>• For people ≥8 years old within six days of COVID-19 symptom onset.</li> <li>• Patients are to report their results to their prescriber in order to have results sent to the public health authorities.</li> <li>• For detailed instructions visit <a href="https://www.fda.gov/media/146313/download">https://www.fda.gov/media/146313/download</a>.</li> </ul>
<b>Antigen tests for rapid detection of COVID-19 authorized for POC use</b> (Negative results do NOT rule out COVID-19, especially in patients with symptoms. If necessary, confirm with a molecular test.)			
<i>BD Veritor System for Rapid Detection of SARS-CoV-2</i> <sup>11</sup>  Results: ~15 minutes	<b>Storage:</b> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <b>Operation</b> (if refrigerated, bring to room temp for use): <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch until just before use.</li> <li>• Swab both nostrils with the same swab.</li> <li>• After processing the swab in the extraction reagent, tests must be run within 30 minutes.</li> <li>• Interpret results between 15 and 20 minutes after starting the test.</li> <li>• Avoid storing specimens in viral transport media.</li> </ul>

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
<b>Antigen tests for rapid detection of COVID-19 authorized for POC use, continued</b> (Negative results do NOT rule out COVID-19, especially in patients with symptoms. If necessary, confirm with a molecular test.)			
<i>BinaxNow COVID-19 Ag Card</i> <sup>10</sup> and <i>BinaxNow COVID-19 Ag Card 2</i> <sup>53</sup>  Results: <sup>10,53</sup> ~15 minutes	<b>Storage:</b> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <b>Operation</b> (if refrigerated, bring to room temp for use): <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• <i>BinaxNow COVID-19 Ag Card</i> is indicated for use in symptomatic patients within 7 days of symptom onset.<sup>49</sup></li> <li>• <i>BinaxNow COVID-19 Ag Card 2</i> is indicated for serial testing twice over three days with at least 36 hours between tests in patient with or without symptoms.<sup>49</sup></li> <li>• Do NOT open the pouch until just before use.<sup>10,53</sup></li> <li>• Swab both nostrils with the same swab.<sup>10,53</sup></li> <li>• Run test within one hour of specimen collection.<sup>10,53</sup></li> <li>• Interpret results between 15 and 30 minutes after starting the test.<sup>10,53</sup></li> <li>• Avoid storing specimens in viral transport media.<sup>10,53</sup></li> <li>• Results of both tests can be captured with the NAVICA app.<sup>49</sup></li> </ul>
<i>Celltrion DiaTrust COVID-19 Ag Rapid Test</i> <sup>41</sup>  Results: ~15 minutes	<b>Storage:</b> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <b>Operation</b> (if refrigerated, bring to room temp for use): <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch more than one hour before use.</li> <li>• When collecting the specimens, swab one or both nostrils. If both nostrils are swabbed, use the same swab.</li> <li>• Interpret results between 15 and 20 minutes after starting the test.</li> <li>• If test is not run immediately after collection, specimens can be stored in extraction buffer at room temp for up to four hours.</li> </ul>
<i>CareStart COVID-19 Antigen</i> <sup>22</sup>  Results: ~10 minutes	<b>Storage:</b> <ul style="list-style-type: none"> <li>• 34°F to 86°F (1°C to 30°C)</li> </ul> <b>Operation</b> (if refrigerated, bring to room temp for use): <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch until just before use.</li> <li>• When collecting nasal swab specimens, swab both nostrils with the same swab. (Only one nostril for nasopharyngeal specimens.)</li> <li>• Interpret results between 10 and 15 minutes after starting the test.</li> <li>• If test is not run immediately after collection, specimens can be stored in extraction buffer at room temp for ≤4 hours.</li> </ul>
<i>Clip COVID Rapid Antigen Test</i> <sup>29</sup>  Results: ~30 minutes	<b>Storage and Operation:</b> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open pouch until just before use.</li> <li>• Swab both nostrils with the same swab.</li> <li>• Run test within 30 minutes of specimen collection.</li> <li>• Interpret results between 15 and 20 minutes after starting the test.</li> <li>• Avoid storing specimens in viral transport media.</li> </ul>

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
<b>Antigen tests for rapid detection of COVID-19 authorized for POC use, continued</b> (Negative results do NOT rule out COVID-19, especially in patients with symptoms. If necessary, confirm with a molecular test.)			
<i>LumiraDx SARS-CoV-2 Ag Test</i> <sup>14</sup>  Results: ~12 minutes	<b>Storage:</b> • 36°F to 86°F (2°C to 30°C)  <b>Operation</b> (if refrigerated, bring to room temp for use): • 59°F to 86°F (15°C to 30°C) and relative humidity of 10% to 90%.	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open pouch until just before use.</li> <li>• Swab both nostrils with the same swab (nasal swab specimens). One or both nostrils can be swabbed for nasopharyngeal specimens.</li> <li>• If test is not run immediately after collection, specimens can be stored at room temp for up to five hours.</li> </ul>
<i>SCoV-2 Ag Detect Rapid Test</i> <sup>50</sup>  Results: ~25 minutes	<b>Storage and Operation:</b> • 59°F to 86°F (15°C to 30°C)	<ul style="list-style-type: none"> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• For use in patients with suspected COVID-19 within five days of symptom onset.</li> <li>• Can be used with serial testing, twice within three days ensuring 24 to 48 hours between tests in people without symptoms.</li> <li>• Do NOT open pouch until just before use.</li> <li>• Swab both nostrils with the same swab.</li> <li>• Interpret results between 20 and 25 minutes after starting the test.</li> <li>• If test is not run immediately after collection, specimens can be stored:               <ul style="list-style-type: none"> <li>• at room temp for up to <b>four hours</b>.</li> <li>• refrigerated for up to <b>four days</b>.</li> </ul> </li> </ul>
<i>Sofia SARS Antigen FIA</i> <sup>12</sup>  Results: ~15 minutes	<b>Storage and Operation:</b> • 59°F to 86°F (15°C to 30°C)	<ul style="list-style-type: none"> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open pouch until just before use.</li> <li>• Use one nostril (the one with the most secretion) to collect sample.</li> <li>• If test is not run immediately after collection, <b>unprepared specimens</b> can be stored at room temp or refrigerated for up to 48 hours.</li> <li>• <b>Prepared specimens</b> can be stored out of direct sunlight, at room temp, for up to one hour before testing.</li> <li>• Not recommended for use with viral transport media as this may decrease sensitivity (increase the chance for a false negative).</li> </ul>

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
<b>Antigen tests for rapid detection of COVID-19 authorized for POC use, continued</b> (Negative results do NOT rule out COVID-19, especially in patients with symptoms. If necessary, confirm with a molecular test.)			
<i>QuickVue SARS Antigen Test</i> <sup>26</sup>  Results: ~10 minutes	<b>Storage and Operation:</b> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch more than one hour before use.</li> <li>• Swab both nostrils with the same swab.</li> <li>• Interpret results between 10 and 15 minutes after starting the test.</li> <li>• If test is not run immediately after collection, <b>unprepared specimens</b> can be stored:               <ul style="list-style-type: none"> <li>• at room temp or refrigerated for up to 120 hours. Bring refrigerated samples to room temp before testing.</li> </ul> </li> <li>• Not recommended for use with viral transport media.</li> </ul>
<b>Antigen tests for rapid detection of COVID-19 and Influenza A/B for POC use</b> (Negative results do NOT rule out COVID-19, especially in patients with symptoms. If necessary, confirm with a molecular test.)			
<i>BD Veritor System for Rapid Detection of SARS-CoV-2 &amp; Flu A+B</i> <sup>42</sup>  Results: ~15 minutes	<b>Storage:</b> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <b>Operation</b> (if refrigerated, bring to room temp for use): <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch more than five minutes before use.</li> <li>• Run test within 30 minutes of specimen collection.</li> <li>• Interpret results between 15 and 20 minutes after starting the test.</li> <li>• Not recommended for use with viral transport media.</li> </ul>
<i>Sofia 2 Flu + SARS Antigen FIA</i> <sup>24</sup>  Results: ~15 minutes	<b>Storage and Operation:</b> 59°F to 86°F (15°C to 30°C)	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> <li>• nasal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch until just before use.</li> <li>• Use one nostril (the one with the most secretion) to collect sample.</li> <li>• Interpret results between 15 and 30 minutes after starting the test.</li> <li>• If test is not run immediately after collection, <b>unprepared specimens</b> can be stored:               <ul style="list-style-type: none"> <li>• at room temp or refrigerated up to 48 hours. Bring refrigerated samples to room temp before testing.</li> </ul> </li> <li>• Not recommended for use with viral transport media.</li> </ul>
<i>Status COVID-19/Flu</i> <sup>43</sup>  Results: ~15 minutes	<b>Storage:</b> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <b>Operation</b> (if refrigerated, bring to room temp for use): <ul style="list-style-type: none"> <li>• 64°F to 86°F (18°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• nasopharyngeal swab</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch until just before use.</li> <li>• Interpret results between 15 and 20 minutes after starting the test.</li> <li>• If test is not run immediately after collection, <b>unprepared specimens</b> can be stored:               <ul style="list-style-type: none"> <li>• at room temp for up to four hours.</li> <li>• refrigerated for up to eight hours. Bring refrigerated samples to room temp before testing.</li> </ul> </li> <li>• Not recommended for use with viral transport media.</li> </ul>

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
<p align="center"><b>Serology (antibody) tests for rapid detection of an immune response to a recent exposure to SARS-CoV-2</b>            (Should generally NOT be used to diagnose COVID-19. <b>Positive results do not mean patients are immune or protected from reinfection.</b>)            Available POC serology tests provide <b>qualitative (yes/no)</b>; not quantitative (number of antibodies) results.            When using fingerstick POC samples for antibody testing, tests should be <b>run immediately after sample collection.</b></p>			
<p><i>Assure COVID-19 IgG/IgM Rapid Test</i><sup>16</sup></p> <p>Results: ~15 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <p><b>Operation</b> (if refrigerated, bring to room temp for use):</p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• fingerstick</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch until just before use.</li> <li>• Interpret results between 15 and 30 minutes after starting the test.</li> <li>• Confirm positive results with a different IgG or IgM assay, due to the risk of false positive results from cross-reactivity with other antibodies.</li> </ul>
<p><i>Megna Health Rapid COVID-19 IgM/IgG Combo Test Kit</i><sup>33</sup></p> <p>Results: ~15 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 39°F to 86°F (4°C to 30°C)</li> </ul> <p><b>Operation</b> (if refrigerated, bring to room temp for use):</p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• fingerstick</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch until just before use.</li> <li>• Interpret results between 15 and 20 minutes after starting the test.</li> </ul>
<p><i>MidaSpot COVID-19 Antibody Combo Detection Kit</i><sup>31</sup></p> <p>Results: ~20 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 39°F to 77°F (4°C to 25°C)</li> </ul> <p><b>Operation</b> (if refrigerated, bring to room temp for use):</p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• fingerstick</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch more than 15 minutes before use.</li> <li>• Interpret results between 18 and 25 minutes after starting the test.</li> </ul>
<p><i>RapCov Rapid COVID-19 Test</i><sup>20</sup></p> <p>Results: ~15 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <p><b>Operation</b> (if refrigerated, bring to room temp for use):</p> <ul style="list-style-type: none"> <li>• 68°F to 77°F (20°C to 25°C)</li> </ul>	<ul style="list-style-type: none"> <li>• fingerstick</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT use if onset of symptoms was &lt;15 days ago.</li> <li>• Do NOT open the pouch until just before use.</li> <li>• Interpret results between 15 and 20 minutes after starting the test.</li> </ul>

POC Test/ Timing for Results	Kit Storage/ Operational Temperature	Specimen Collection	Comments
<p align="center"><b>Serology (antibody) tests for rapid detection of an immune response to a recent exposure to SARS-CoV-2, continued</b>            (Should generally NOT be used to diagnose COVID-19. <b>Positive results do not mean patients are immune or protected from reinfection.</b>)            Available POC serology tests provide <b>qualitative (yes/no)</b>; not quantitative (number of antibodies) results.            When using fingerstick POC samples for antibody testing, tests should be <b>run immediately after sample collection.</b></p>			
<p><i>RightSign COVID-19 IgG/IgM Rapid Test Cassette</i><sup>32</sup></p> <p>Results: ~10 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <p><b>Operation</b> (if refrigerated, bring to room temp for use):</p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• fingerstick</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch more than one hour before use.</li> <li>• Interpret results between 15 and 20 minutes after starting the test.</li> <li>• Test may be less accurate if used in patients whose onset of symptoms was &lt;15 days ago.</li> </ul>
<p><i>SGTi-flex COVID-19 IgG</i><sup>34</sup></p> <p>Results: ~10 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <p><b>Operation</b> (if refrigerated, bring to room temp for use):</p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• fingerstick</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch until just before use.</li> <li>• Interpret results between 10 and 30 minutes after starting the test.</li> <li>• Test may be less accurate if used in patients whose onset of symptoms was &lt;15 days ago.</li> </ul>
<p><i>Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test</i><sup>13</sup></p> <p>Results: ~10 minutes</p>	<p><b>Storage:</b></p> <ul style="list-style-type: none"> <li>• 36°F to 86°F (2°C to 30°C)</li> </ul> <p><b>Operation</b> (if refrigerated, bring to room temp for use):</p> <ul style="list-style-type: none"> <li>• 59°F to 86°F (15°C to 30°C)</li> </ul>	<ul style="list-style-type: none"> <li>• fingerstick</li> </ul>	<ul style="list-style-type: none"> <li>• Do NOT open the pouch more than one hour before use.</li> <li>• Interpret results between 10 and 20 minutes after starting the test.</li> </ul>

**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.<sup>1</sup>
- In the U.S., pharmacies can use the following CPT code for POC COVID-19 testing: U0002.<sup>2</sup> 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 waiver, 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.<sup>21</sup> 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]).<sup>3</sup>
- 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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*Users of this resource are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and internet links in this article were current as of the date of publication.*

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