

# COVID-19 Self-Collected Antibody Test System

## Collection Kit Instructions for Use

- For in vitro diagnostic only
- For use by individuals age 18 years or older or by adults collecting specimens from individuals 5 years of age and older.

### Lay out the contents of the kit.

#### Dried-Blood Spot (DBS) Card

Clearly label the card with your full name and today's date

#### Alcohol Wipes

Open packages and place wipes on the table

#### Sterile Gauze

Open packages and place gauze on the table

#### Adhesive Bandage

Open packages and place bandage on the table

#### Pressure-activated Lancets


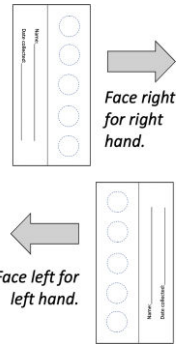

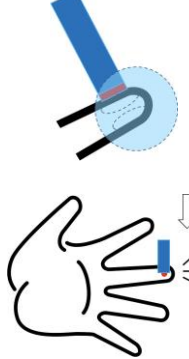

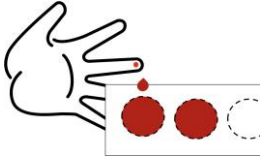

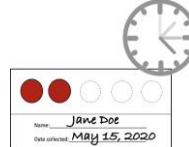


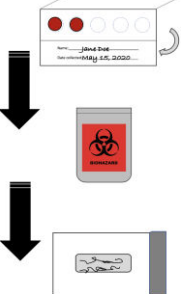
Remove the clear cap from one safety lancet

#### Biohazard Bag

Open the bag and keep the desiccant packet inside

#### Return Envelope

Place on table in preparation for Step 9

<p><b>Step 1</b></p> <p>We recommend the following steps be completed before collection:</p> <ul style="list-style-type: none"> <li>• Drink plenty of water.</li> <li>• Wash hands with soap and warm water. <b>Leave collection hand under warm water for 60 seconds while opening and closing your hand (make a fist motion repeatedly).</b></li> <li>• Rub hands together to warm hands or windmill arm 5-10 times.</li> </ul> 	<p><b>Step 2</b></p> <p>Open the dried blood spot card.</p> <p>Lay it vertical with the spots in the direction of the hand you will collect from.</p> 	<p><b>Step 3</b></p> <p>Use the middle or ring finger.</p> <p>Disinfect the side of the fingertip with the provided alcohol wipe and allow it to dry at least 15 seconds.</p> 
<p><b>Step 4</b></p> <p><b>Note:</b> Any hesitation may activate the lancet too early and not penetrate deep enough.</p> <p>Place the red end of the lancet on the disinfected side of your fingertip. It may help to place your finger against a hard surface to keep it steady.</p> <p>Without hesitation, press the lancet towards your finger (with your finger also pushing into the lancet) until an audible click is heard.</p> 	<p><b>Step 5</b></p> <p><b>Note:</b> Do not press finger onto card</p> <p>Using your other hand, apply firm pressure on the pricked finger from below the puncture site to allow for a large drop of blood to form.</p> <p>Use the provided gauze pad to wipe away the first drop.</p> <p>Continue applying pressure below the puncture site, releasing intermittently, to allow the blood to collect. <b>Lightly touch the DBS card with the blood, paying attention to not let finger touch card.</b></p> 	<p><b>Step 6</b></p> <p><b>Note:</b> Incorrectly collected blood samples may not be usable for testing.</p> <p>Completely fill at least 2 of the circles on the DBS card. <b>Collect a third spot when possible.</b></p> <p>If you do not have enough blood from the first fingerstick, use an additional lancet and a different finger to collect another sample as per steps 3 through 5.</p> 
<p><b>Step 7</b></p> <p><b>Reminder:</b> Write your full name, date of birth, and today's date on the card.</p> <p>When finished, hold the gauze on the fingertip to stop the bleeding.</p> <p>Use the provided bandage.</p> <p>Leave the card open and allow 30 minutes to air dry before closing the flap.</p>  	<p><b>Step 8</b></p> <p>Dispose of used materials in the trash.</p> <p>Samples must be completely dry before proceeding to step 9. Samples that do not completely fill the circles (as shown on the right) or are not dry may not be usable for testing.</p>  	<p><b>Step 9</b></p> <p><b>Mail samples within 48 hrs of collection.</b></p> <ol style="list-style-type: none"> <li>1. Close the card and place in the provided biohazard bag.</li> <li>2. Place biohazard bag back into the 4U Health shipping box.</li> <li>3. Insert 4U Health box into the shipping bag, seal bag and affix shipping label.</li> <li>4. Drop in the nearest mailbox or deliver to your favorite post office, unless you purchased FedEx overnight delivery.</li> </ol> 

• This self-collection kit is used as part of a test system. This test system has not been FDA cleared or approved but has been authorized for emergency use by FDA.

• This test system has been authorized only for detecting IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens; and

• The emergency use of this test system is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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