HRSA Rural Health Clinic COVID-19 Testing Supply Program Frequently Asked Questions (FAQs)

The U.S. Department of Health and Human Services (HHS) announced that all Medicare-certified Rural Health Clinics (RHCs) are invited to order free, Food and Drug Administration (FDA)-approved COVID-19 self-testing supplies for distribution in their communities through the Health Resources and Services Administration's (HRSA) COVID-19 Testing Supply Program.

For additional assistance, please email HRSA at <u>RHCTestKit@hrsa.gov</u> or the National Association of Rural Health Clinics (NARHC) at <u>rhccovidsupplies@narhc.org</u>.

General

1. What is the HRSA COVID-19 Testing Supply Program? (Added: 2/7/2022)

Consistent with the Biden Administration's "Path Out of the Pandemic," HHS is providing free, at-home self-tests to federal qualified health centers and CMS-certified Rural Health Clinics (RHCs), for distribution at no cost to patients and community members. The program is intended to ensure COVID-19 tests are made available to populations and settings in need of testing, especially populations at greatest risk from adverse outcomes related to COVID-19. As of December 21, 2021, all HRSA-supported health centers (including look-alikes) and CMS-certified RHCs are eligible to participate in the program after completing the onboarding process.

2. Why are CMS-certified RHCs encouraged to participate in the HRSA COVID-19 Testing Supply Program? (*Added: 2/7/2022*)

Approximately 4,800 CMS-certified RHCs ensure primary care access and improve health outcomes for the estimated 62 million Americans who live in rural communities.

In order to ensure those most at risk to COVID-19 have access to at-home self-testing supplies, and to support greater COVID-19 mitigation efforts, all federally qualified health centers and CMS-certified RHCs are eligible to receive and distribute at-home self-tests to patients and members of their communities.

3. Are RHCs required to receive testing supplies through this program? (Added: 2/7/2022)

No, this is a voluntary program. CMS-certified RHCs that choose to register with HRSA and place orders through the online ordering system will receive the COVID-19 at-home self-tests and any additional testing supplies that may become available.

Enrollment

4. Who is eligible for this program? (Added: 2/7/2022)

Active RHCs that are <u>certified by CMS</u>, have CMS Certification Numbers (CCNs), and are listed in the CMS Survey & Certification's Quality, Certification and Oversight Reports (QCOR), and organizations that own and operate RHCs meeting these qualifications, are eligible for this program. To verify your eligibility, <u>visit the CMS Quality</u>, <u>Certification and Oversight Reports</u> (QCOR) website. On the site, you can verify that your information is correct and your provider type is listed as an RHC.

5. I am interested in signing up to receive free COVID-19 self-testing supplies. How do I register? (Added: 2/7/2022)

- Confirm that you are a CMS-certified RHC and identify your CMS Certification Number (CCN) and the CCNs provided to HRSA match the CMS certification number in QCOR <u>https://qcor.cms.gov/basic_research.jsp</u>
 - a. If you are unable to provide correct CCNs for your RHCs, we encourage you reach out to the National Association of Rural Health Clinics (NARHC) for assistance at rhccovidsupplies@narhc.org
- 2. Visit the <u>online registration</u> to provide FORHP with some basic information about your RHC including shipping address and hours of operation.
- Complete the HRSA COVID-19 Testing Supply Program Conditions of Participation Agreement Please contact <u>rhccovidsupplies@narhc.org</u> if you require a blank COP form or have any questions.
 - a. Check the COP certification boxes on page 3 and 4 (noted in red on the COP).
 - b. Return the COP to <u>RHCTestKit@hrsa.gov</u>

DPOP Test Kit Ordering and Delivery

- 6. What is the Diagnostics Ordering Portal (DPOP) and HPOP? (Added: 2/7/2022) DPOP or the Diagnostics Ordering Portal is an online system utilized by both participating RHCs and HRSA to place supply test kit orders, manage contact information, and store data. Once registered for the HRSA COVID-19 Testing Supply Program, RHCs may access their DPOP account here: https://vpop.cdc.gov/account/signin/. DPOP operates under the umbrella program HPOP, Health Partner Order Portal, which includes VPOP, Vaccine Ordering Portal. RHCs that are participating in both the vaccine and testing supply programs can access both through the same login and provider page. HPOP and its various components were developed by the computer software company, Oracle.
- 7. Once I am registered for the program, how do I order test kits? (Added: 2/7/2022) Test kit orders are placed through a system called DPOP. Once the RHC's Conditions of Participation and online registration forms are reviewed for enrollment, the supplied contact email will receive a link from <u>vpop-no-reply@cdc.gov</u> to activate their account. Once activated, providers will be able to login to the portal and submit test kit orders. This is accomplished by going to the provider page, clicking "create new order" under "diagnostic orders", and selecting the desired quantity. Test kit orders are no longer accepted via email.
- 8. Can I place an order via email? (*Added: 2/7/2022*)

No. Test kit orders are not currently accepted via email. If you require assistance placing orders in DPOP, please contact <u>RHCTestKit@hrsa.gov</u> or <u>rhccovidsupplies@narhc.org</u>.

9. How long does it normally take before our point of contact will receive the email to create the DPOP account for our RHC? How will I know when I am registered and able to order test kits? (Added: 2/7/2022)

All submitted enrollment documentation is reviewed within 7-10 days. Barring issue, RHCs will be uploaded into DPOP and receive an account activation email. Issues with documentation will be communicated upon review. Once the RHC activates their account via the HPOP email link, they will be able to place their own orders in the DPOP system.

10. I placed my order in the last three weeks, when will my order be delivered? (*Added: 2/7/2022*) We appreciate RHCs mobilizing quickly to order and distribute self-tests. All orders made by RHCs prior to the January 4th ordering deadline have been processed and shipped. If you have

NOT received an order placed prior to the January 4th, 2022 deadline, please email <u>RHCTestKit@hrsa.gov</u>.

In light of the significant demand for at-home tests, we will be setting aside orders from the last cycles (Jan. 11 and Jan. 18) that have not already been shipped by the vendor to ensure equitable distribution of supply. New orders can currently be placed by the affected RHCs for next week's cycle.

11. I am having difficulty accessing/navigating DPOP. How do you recommend I proceed? (*Added:* 2/7/2022)

- If you have not received a link to activate your account, but did receive confirmation of program enrollment; log in with the RHC contact email, select "forget password", and reset password : <u>https://vpop.cdc.gov/account/signin/</u>
- If you are having issues navigating DPOP, please send your questions to <u>RHCTestKit@hrsa.gov</u>. We apologize for the confusion and thank you for your patience.

12. How do I update my inventory in DPOP? (Added: 2/7/2022)

Participating RHCs are required to report stock on hand weekly in DPOP per the signed Conditions of Participation. To make a new entry:

- 1. Log into your DPOP account here: <u>https://vpop.cdc.gov/account/signin/</u>
- 2. Navigate to each site's "Provider Details" section
- 3. Under "Diagnostic Inventory" select "Diagnostic Stock on Hand" tab
- 4. Select "Add Diagnostic Stock" and update accordingly

RHCs are NOT required to enter information in the "Diagnostics Administered" tab or provide lot numbers. Inventory currently cannot be retroactively entered in "Stock on Hand". Stock is saved on the date the RHC logs it in DPOP. HRSA is working to update the DPOP system to display a full history of the organizations' stock on hand entries. Stay tuned and please continue updating you stock each week.

13. We have access to DPOP but the ordering button for testing supplies does not appear to be working. (*Added: 2/7/2022*)

Upon receiving access to DPOP, your RHC's site points of contact <u>must</u> verify each site's delivery address, ability to accept a 53-foot trailer, hours of operation, and any special delivery instructions. Once this is completed, you will be able to use DPOP to order at home/self-test kits. As a reminder, you are encouraged to review and verify this information on a regular basis to ensure accurate delivery of testing supplies.

14. How do we verify our site address and hours in DPOP? (Added: 2/7/2022)

You must verify your site address(es) and site hours to place an order in DPOP for testing supplies. To verify your site address,

- 1. Log into your DPOP account here: https://vpop.cdc.gov/account/signin/
- 2. Navigate to each site's "Provider Details" section
- 3. Select the "Physical" next to the address
- 4. Select the "Diagnostic" box at the top of the page, review all the address and hour information
- 5. Click "Apply Changes" at the bottom
- 6. You should then receive a green check mark stating the information is verified

15. How do I change/manage my shipping address in DPOP? (Added: 2/7/2022)

Delivery addresses can be edited on the individual provider's page by the RHC. To accomplish this,

- 1. Log into your DPOP account here: https://vpop.cdc.gov/account/signin/
- 2. Navigate to each site's "Provider Details" section
- 3. Select the "Physical" next to the address
- 4. Select the "Diagnostic" box at the top of the page
- 5. Enter the correct address and delivery hours
- 6. Click "Apply Changes" at the bottom

16. How many test kits can I order? (Added: 2/7/2022)

- The minimum order is 5 shippers (225 tests kits). Maximum order quantities will be displayed in DPOP each week and may vary from week to week depending on product availability.
- Orders can be placed in multiples of individual shippers (45 test kits per shipper) or pallets (1,350 test kits per pallet).
- Each test kit contains two COVID-19 rapid antigen tests and is intended for one individual.

17. How large are the physical order shipments? (Added: 2/7/2022)

- A shipper (45 test kits) is 22.5 lbs with dimensions 19-3/4 L x 15-1/4 W x 9-1/2 H (inches).
- A pallet (1,350 test kits) is approximately 675 lbs with dimensions 48 L x 40 W x 56 H (inches). Each pallet contains 30 shippers.

18. What kind of tests are available through this program? (Added: 2/7/2022)

- Quidel QuickVue[®] intended for the qualitative detection of the nucleocapsid proteins from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 36 hours between tests
 - Rapid antigen test that an individual can self-administer at home
 - Results available within 10 minutes
 - Can be used if symptomatic, asymptomatic, or within 6 days of symptom onset
 - Can be self-administered for use by those 14 years of age and older and for those 2-13 years of age, if an adult performs the test
 - Visual instructions included with each test kit

19. What are the storage requirements for the test kit and how long do they last? (Added:

2/7/2022)

- Test kits must be stored at room temperature (15-25°C/59-77°F)
- Quidel QuickVue test kits have a shelf life of one year
- For specific product questions, please contact the Quidel help desk at 1-800-874-1517 (Option 2, then Option 5), operating 7:00am-5:00pm PT Mon-Friday.

20. I'd like to order tests, but our building can't store them all. Can I have them delivered to a different location? What if we can't fit a trailer for delivery? (Added: 2/7/2022)

- RHCs may provide a different address for delivery as long as someone from their organization is there to accept and manage them. The registered RHC must be the primary custodian, however, they are welcome to share and distribute with other facilities.
- If your facility cannot accommodate a trailer for delivery of the tests, we ask that you please order less than a pallet of tests per ordering cycle.

21. How do I track the shipment of my order? (Added: 2/7/2022)

- Order tracking information will be available in the online ordering portal, DPOP, after your order has been shipped from the test kit vendor, Quidel. Currently, order shipment and delivery may take approximately 10 to 14 days from the order processing date
- View the order tracking information for an order by selecting each order for a site within HPOP and scrolling to the bottom of the page to the "Shipping" section. We are working to add system functionality that will indicate the status of the order as "shipped" (instead of remaining in "transmitted" status) once the order is shipped. If you see a Quidel Order number (ex. D00XXXXX) in the Shipping Information section, this means the order is in process with Quidel.
- If your shipment is damaged or is missing any kits, please contact Quidel at 1-800-874-1517 (Option 1, then Option 1) between 7:00am to 5:00pm PT, Monday- Friday

Program Policy

22. How do I know who I can distribute tests to? (Added: 2/7/2022)

- This program is intended to ensure COVID-19 tests are made available to populations and settings in need of testing, especially populations at greater risk from adverse outcomes related to COVID-19. Rural Health Clinics should generally avoid making arrangements with local employers to provide an ongoing supply of at-home test kits in order for that employer to fulfill their legal obligation for employee testing. As RHCs distribute the at-home self-tests, they should provide information about how and when to use the tests and what to do if a test is positive, including how the individual may contact the RHC for assistance. Individuals may use the self-test immediately (e.g. in the RHC with or without the clinician present or at-home) or when appropriate at a future time (please note that tests expire after one year). For information regarding self-testing, please refer to the <u>CDC Self-Test webpage</u>. Examples of intended COVID-19 at-home self-test recipients include but are not limited to:
- Health care for the homeless mobile clinics, street medicine teams, and field-based case management teams.
- Agricultural worker programs.
- Individuals visiting nursing home patients, traveling to see elderly adults or small children, and/or who are asymptomatic with known exposure.
- Homebound patients during home visits or as a leave-behind after a visit.
- Essential workers, such as childcare providers, teachers, and health workers in long-term care facilities.
- RHCs where there are no large pharmacies or grocery stores nearby.
- Residents of HUD-assisted housing
- Individuals living in congregate settings, such as nursing homes, adult foster care, and college dorms.

23. Are there any program guidelines or requirements? (Added: 2/7/2022)

The HRSA COVID-19 Testing Supply Program does not have testing distribution requirements. RHCs are encourage to use their best discretion in distributing at-home self-tests to the local community and RHC service area.

24. Can we provide tests to our RHC staff members or other non-patients? (Added: 2/7/2022) RHCs should use their best discretion in distributing at-home self-tests to the local community and RHC service areas. The program is intended to ensure COVID-19 at-home self-tests are made available to RHC patients, and community populations and settings in need of testing, especially populations at greater risk from adverse outcomes related to COVID-19. This may include non-patients or RHC staff. Local employers should review OSHA's COVID-19 Vaccination and Testing Emergency Temporary Standard (ETS) for guidance regarding their legal obligation for employee testing.

25. Can I share tests with other organizations? (Added: 2/7/2022)

Yes. Tests may be shared with other organizations, RHCs and non-RHCs alike. If tests are transferred to another entity, please update your RHC's "diagnostic stock on hand" under "diagnostic inventory" on your provider page in DPOP accordingly.

- 26. Can I sell tests to other organizations? (Added: 2/7/2022)No. Tests may not be sold under this HRSA COVID-19 Testing Supply Program.
- 27. What are the DPOP inventory reporting requirements? (Added: 2/7/2022)

Participating RHCs are required to report stock on hand weekly in DPOP per the signed Conditions of Participation. To make a new entry:

- 1. Log into your DPOP account here: https://vpop.cdc.gov/account/signin/
- 2. Navigate to each site's "Provider Details" section
- 3. Under "Diagnostic Inventory" select "Diagnostic Stock on Hand" tab
- 4. Select "Add Diagnostic Stock" and update accordingly

RHCs are NOT required to enter information in the "Diagnostics Administered" tab or provide lot numbers. Inventory currently cannot be retroactively entered in "Stock on Hand". Stock is saved on the date the RHC logs it in DPOP. HRSA is working to update the DPOP system to display a full history of the organizations' stock on hand entries. Stay tuned and please continue updating you stock each week.

28. Do we need to log individual patient usage and positive test results? (Added: 2/7/2022)

The HRSA RHC Testing Supply Program requires regular inventory updates in the Diagnostic Ordering Portal (DPOP). RHC distribution tracking and record keeping is at the RHC discretion. HRSA does not provide specific over-the-counter test kit reporting guidance. HRSA highly encourages RHCs review the local state and county guidelines. Many request positive test reports and vary on guidance. The Centers for Disease Control (CDC) provides ongoing, updated guidance on Testing Strategies for SARS-CoV-2 as well as webpage links to State Departments of Health in order to learn more about state laws, rules, and regulations where applicable. RHCs are may institute additional RHC patient requirements (e.g. reporting requirements) at the RHC discretion. Please review your Conditions of Participation for additional details.

29. What are the FDA EUA requirements for use of testing supplies? (Added: 2/7/2022) On March 31, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the QuickVue At-Home OTC COVID-19 Test. Under FDA EUA guidance, "Individuals should provide all test results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC."

30. What are my state reporting requirements? (*Added: 2/7/2022*)

HRSA highly encourages RHCs review the local state and county guidelines and consult with local public health entities. Many request positive test reports and vary on guidance. The Centers for Disease Control (CDC) provides ongoing, updated guidance on <u>Testing Strategies for SARS-CoV-2</u> as well as webpage links to various State Departments of Health in order to learn more about state laws, rules, and regulations where applicable. RHCs may institute additional RHC patient requirements (e.g. reporting requirements) at the RHC discretion.

31. Do you have a policy and procedures template? (*Added: 2/7/2022*)

No. HRSA does not currently provide a specific policy or procedures template. RHCs are encourage to shape their internal policies as best suited for their practice and in accordance with local and state guidelines. For further questions, please contact rhccovidsupplies@narhc.org.

32. Can RHCs add their logo to test kits and strike out bar code information to prevent redistribution of the kits? (*Added: 2/7/2022*)

Yes. If RHCs wish to add their logo to the test kit prior to distributing them in the community, they may do so. Please do not make any changes to the instructions and documentation that is included with the test kits.

A RHCs may also choose to strike out the bar code information on the test kit box (such as by drawing a black line through it). Tests are available at no cost to Rural Health Clinic patients and their community. The tests should not be sold by recipients to other individuals. A recipient of the test may choose to share the test kit with other family and/or community members as needed.

ACRONYM KEY:

CCN: CMS certification number CDC: Centers for Disease Control CMS: Centers for Medicare and Medicaid Services COP: Conditions of participation COVID-19: Coronavirus disease 2019 DPOP: Diagnostics Provider Ordering Portal EUA: Emergency Use Authorization FDA: Food and Drug Administration HHS: Department of Health and Human Services HPOP: Health Partner Ordering Portal HRSA: Health Resources and Services Administration NARHC: National Association of Rural Health Clinics OSHA: Occupational Safety and Health Administration RHC: Rural Health Clinic TA: Technical assistance QCOR: Quality, Certification and Oversight Reports VPOP: Vaccine Provider Ordering Portal