

**TO:** Vermont Pharmacists and Other Health Care Providers, Vermont Healthcare Facilities  
**FROM:** Jennifer S. Read, MD, FIDSA, Medical Epidemiologist

### **Pharmacist Ordering and Administration of Testing for COVID-19 in Vermont**

The U.S. Department of Health & Human Services (DHHS) has issued guidance under the Public Readiness and Emergency Preparedness Act (“the PREP Act”) authorizing pharmacists to order and administer COVID-19 tests. See the [HHS Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act](#) and [FDA’s Emergency Use Authorizations](#).

Pursuant to [Executive Order 01-20, §§ 15-16](#), the Commissioner of Health and the Secretary of State authorize Vermont pharmacists to order and administer COVID-19 tests approved by FDA for pharmacy-based sample collection or administration. Pharmacies must abide by all FDA guidance and updates when using point-of-care testing instruments. Find the Board of Pharmacy COVID-19 Emergency Guidance [here](#).

#### **REQUIRED ACTIONS:**

If pharmacy-based COVID-19 testing is planned, ensure that the following are addressed:

- 1. Who can be tested:** Pharmacy-based COVID-19 testing is appropriate only for asymptomatic individuals. Symptomatic persons should remain at home and contact their health care provider (or call 2-1-1 if they have no primary care provider) for further guidance. Any public notice or advertisement for pharmacy-based testing should contain this instruction.
- 2. Where can sample collection occur:** Sample collection for COVID-19 testing shall occur in separately designated patient testing areas outside of pharmacies, such as drive-up windows or parking lots.
- 3. To whom must test results be reported:**
  - a. To the Vermont Department of Health:
    - i. A pharmacy offering COVID-19 testing must report test results to the Health Department, as required by [the Board of Pharmacy COVID-19 Emergency Guidance](#), and per the below specifications and the Health Department [Reportable and Communicable Diseases Rule](#), CVR 13-140-007.
    - ii. Results shall be reported using HL-7 messaging or CSV file format consistent with Health Information Exchange requirements. To configure one of these options please contact: [AHS.VDHELRSupport@vermont.gov](mailto:AHS.VDHELRSupport@vermont.gov).
    - iii. A pharmacy that collects samples for submission to a reference laboratory must ensure that the laboratory has a reliable process for reporting results to the Health Department. If the pharmacy uses a point-of-care testing instrument, or a laboratory that does not submit results to the Health

Department, it is the responsibility of the pharmacy to ensure the results are delivered in one of the two accepted formats listed in ii.

- iv. Pharmacies shipping specimens to a lab should review the CDC guidance [here](#).
- b. To the patient and the primary care provider of record:
  - i. A pharmacy must convey test results to patients and their primary care providers of record within 24 hours of result, in a manner that maintains patient privacy in accordance with the Health Insurance Portability and Accountability Act (HIPAA).
  - ii. A pharmacy that collects samples for submission to a reference laboratory must ensure that the laboratory has a reliable process for conveying test results to patients and their primary care providers within 24 hours of result.
  - iii. The Health Department has [standard-form instructions](#) to support participating pharmacies in conveying negative test results to patients.

#### 4. Clinical Laboratory Improvement Act (CLIA) Certificates of Waiver, Policies and Procedures:

- a. If a pharmacy intends to collect samples for submission *to an outside laboratory*, a CLIA Certificate of Waiver **is not required**. The Health Department Laboratory will not be available at this time to contract with pharmacies.
- b. If a pharmacy intends to collect samples for testing *at the pharmacy*, a CLIA Certificate of Waiver **is required**. See the CMS document [How to Apply for a CLIA Certificate of Waiver](#).
  - i. FDA has clarified that when it grants an Emergency Use Authorization (EUA) for a point-of-care test, that test is deemed to be CLIA-waived. To identify CLIA-waived point-of-care tests:
    - (a.) Access the [FDA's EUA website](#).
    - (b.) Scroll down to find the "In Vitro Diagnostics EUAs."
    - (c.) Under the heading "Authorized Setting(s)," look for tests marked "W."
- c. Pharmacies offering COVID-19 testing must implement policies and procedures to ensure:
  - i. Notification of the test kit manufacturer and FDA (via email to [CDRH-EUAREporting@fda.hhs.gov](mailto:CDRH-EUAREporting@fda.hhs.gov)) in the event of suspected test errors, to include false positive or negative results and any other significant deviations from the established performance characteristics of the test kit;
  - ii. Competent training of staff engaged in specimen collection and testing, including review and understanding of the test kit manufacturer instructions/package insert; and
  - iii. Appropriate use of personal protective equipment (PPE) and environmental security measures to protect staff and patients.
- d. Pharmacies offering COVID-19 testing are encouraged to consult the COVID-19 [Molecular Testing Pharmacy Checklist](#) developed by the Virginia Board of Pharmacy and republished for Vermont pharmacists with the gracious permission of that Board.

**5. Who Can Collect Specimens or Perform Testing:**

- i. Licensed pharmacists, as well as pharmacy interns and registered pharmacy technicians under the direct supervision of a pharmacist, may collect samples and perform point-of-care COVID-19 testing per the Board of Pharmacy COVID-19 Emergency Guidance.
- ii. A pharmacy shall ensure that all personnel participating in sample collection or testing are trained to perform required tasks safely, effectively, and consistently. This includes adherence to the testing device manufacturer's instructions. Completion of training must be documented. For additional information, refer to the CDC website [Guidelines for Clinical Specimens](#) and the Office of the Assistant Secretary for Health (OASH) website [COVID-19 Fact Sheet for Nasal Specimen Collection](#).

- 6. Personal Protective Equipment and Infection Control:** Guidance on infection control measures and PPE appropriate for collection and handling of patient-collected samples is available from [CDC's website](#). Pharmacies are expected to secure their own PPE supply.

If you have any questions, please contact the HAN Coordinator at 802-859-5900 or [vthan@vermont.gov](mailto:vthan@vermont.gov)

**HAN Message Type Definitions**

*Health Alert:* Conveys the highest level of importance; warrants immediate action or attention.

*Health Advisory:* Provides important information for a specific incident or situation may not require immediate action.

*Health Update:* Provides updated information regarding an incident or situation; unlikely to require immediate action.

*Info Service Message:* Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature.