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Policy Area: COVID-19

Key Phrases:

Applicability: St. Lawrence Health system-

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# **HRSA COVID-19 Testing Supply Program**

### **PURPOSE**

As part of the Biden Administration's "Path Out of the Pandemic" <u>COVID-19 Action Plan</u>, the Department of Health and Human Services (HHS) in partnership with the Department of Defense is making available to all HRSA-supported health centers (including look-alikes), as well as Medicare-certified rural health clinics, free COVID-19 at-home self-testing supplies, authorized by the Food and Drug Administration (FDA) for emergency use. Distribution of these self-tests at no cost to health center patients and community members will help to ensure and expand community-based COVID-19 mitigation efforts.

The following policy is intended to ensure COVID-19 at-home self-tests are made available to health center and Medicare-certified rural health clinic patients and community populations and settings in need of testing, especially populations at greatest risk from adverse outcomes related to COVID-19.

Health centers and Medicare-certified rural health clinics should use their best discretion in distributing athome self-tests to the local community.

### SCOPE

All St. Lawrence Health (SLH) affiliate entities and all workforce and non-workforce members including, but not limited to, physicians, contractors, and volunteers.

### **POLICY**

- SLH is required to make use of testing supplies in conformance with the FDA's Emergency Use Authorization (EUA) for the specific test kits provided, the EUA Fact Sheet for Health Care Providers, and all other FDA authorized accompanying materials (and as the FDA may revise the EUA and accompanying materials), and consistent with all requirements, recommendations, and other guidance of HHS.
- 2. SLH and any employee in receipt of testing supplies shall not sell or seek reimbursement for the testing supplies that the federal government provides at no cost to SLH.
- 3. SLH is required to provide the tests regardless of the recipient's ability to pay administration or related fees or coverage status. SLH may not seek any reimbursement, including through balance billing, from the test recipient.
- 4. SLH is required to comply with FDA EUA requirements for use of testing supplies, including ensuring that appropriate storage, inventory management and administration methods are in place. SLH will identify

individuals responsible for ensuring these requirements are met.

- 5. SLH is required to order testing supplies available under the HRSA COVID-19 Testing Supply Program through the HHS-designated systems. SLH must report the number of testing supplies that are in stock, expired, or wasted using the HHS designated diagnostic ordering system. SLH will identify individuals responsible for ensuring that these requirements are met.
- SLH must comply with all applicable federal, state, local or territorial laws that impact the distribution of self-tests or COVID-19 test administration to patients and within the community. SLH must comply with applicable patient assent or consent laws for administration of COVID-19 tests.
- 7. SLH must have processes to ensure timely and proper acceptance of testing supplies. Those processes must include, but are not limited to, procedures for accepting delivery through commercial delivery services. SLH must report any testing supplies that are damaged upon delivery pursuant to the process provided by the delivery service and to HHS within 24 hours. HHS will provide procedures for reporting.
- 8. SLH may use contractors to perform some or all of SLH's duties under Agreement. SLH must ensure that any contractor performs its duties in full compliance with Agreement and SLH is responsible under Agreement for any non-compliance with Agreement by any of its contractors. Furthermore, any knowledge concerning or resulting from performance of Agreement by any of SLH's contractors is imputed to SLH.

### **PROCEDURE**

### Questions about the HRSA COVID-19 Testing Supply Program

For Systems Access Issues, including assistance with navigating DPoP:

- COVID-19 Administration Reporting System (CARS) Help Desk
  - Email: CARS HelpDesk@cdc.gov
  - Phone: 1-833-748-1979
  - 8:00 a.m.-8:00 p.m. ET, Monday-Friday

For Product Questions, including delivery issues and product damage:

- Quidel 1-800-874-1517 (Option 2, then Option 5)
  - 7:00 a.m.-5:00 p.m. PT, Monday-Friday

#### For Policy/Program Questions:

- Health Center Program Support
  - Select: COVID-19 Testing Supply Distribution Program from the dropdown
- Or call: 1-877-464-4772
- 8:00 a.m.-8:00 p.m. ET, Monday-Friday (except federal holidays)

### References/Citations

- For information regarding self-testing, please refer to the <u>CDC Self-Test webpage</u>.
- For information regarding the ordering testing supplies, please refer to <a href="mailto:email:communications to all health">email:communications to all health</a> centers.
- Biden Administration's "Path Out of the Pandemic" COVID-19 Action Plan.

### **Attachments**

No Attachments

## **Approval Signatures**

Approver	Date
Jeremy Slaga: Chief Administrative Officer	pending
Angela Board: Document Control Manager	1/18/2022

# **Applicability**

Canton-Potsdam Hospital, Gouverneur Hospital, Massena Hospital, St. Lawrence Health System

