Long-Term Care Regulatory Provider Letter

Number: PL 20-47
Title: Reporting Guidance for Long-Term Care Providers – Point-of-Care Antigen Testing
Provider Types: Home and Community Support Services (HCSSAs) Licensed to Provide Home Health and Hospice Services
Date Issued: October 26, 2020

1.0 Subject and Purpose

This provider letter outlines responsibilities related to reporting COVID-19 test results for agencies conducting point-of-care (POC) antigen tests.

This letter is **not** intended for use by agencies that do not conduct COVID-19 POC tests at the client's home or independent living environment, in the parent agency, branch office, or alternate delivery site, or the hospice agency operating an inpatient hospice unit. Agencies that do not conduct COVID-19 POC tests in these locations will continue to report positive cases in clients and staff to the local health entity or the Department of State Health Services (DSHS).

2.0 Policy Details & Provider Responsibilities

Home health and hospice agencies conducting a COVID-19 POC antigen test must apply for a Clinical Laboratory Improvement Amendment (CLIA) waiver and report all test results to DSHS and to their local health entity to comply with federal and state requirements. The following sections describe each requirement.

2.1 CLIA Waivers

HCSSAs receiving POC antigen test kits from the U.S. Department of Health and Human Services (HHS), as well as home health and hospice agencies purchasing or receiving POC antigen test kits for

COVID-19, will need to obtain a CLIA Certificate of Waiver before conducting any testing. Agencies can apply for a CLIA waiver by filling out Form CMS-116 and sending it to the regional CLIA licensing group for the zone in which the parent agency is located.

Please note that agencies should fill out section 1 of Form CMS-116 by selecting "Other Changes (Specify)" and fill in "COVID-19 home health" or "COVID-19 hospice" to alert HHSC that the application is part of the HHS effort or related to COVID-19 testing by a long-term care provider. For a new CLIA applicant/application, the "initial" box in section 1 needs to be checked. The definitive information the CLIA team will use to assess a laboratory that is doing SARS-CoV-2 testing will be on the third page of the 116 where waived testing should be listed.

Agencies that have an existing CLIA Certificate of Waiver and are using a waived COVID-19 test are not required to update the CLIA Certificate of Waiver. As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." The Food and Drug Administration determines which tests meet these criteria when it reviews a manufacturer's application for a test system waiver.

2.2 Reporting COVID-19 Test Results:

Agencies performing POC antigen testing related to COVID-19 must report data for all testing completed in accordance with Title 25 Texas Administrative Code §97.2 and Texas Health and Safety Code Chapter 81 for all test results (positive, negative, or indeterminate), and for each individual tested (clients and employees). An agency must report the test results within 24 hours of the results being known or determined, on a daily basis. For days that an agency does not conduct any tests, the agency would not have to submit a report to DSHS.

By reporting to the local health entity and DSHS, a home health or hospice agency that conducted the COVID-19 testing should not have to report test result information to the CDC except as described in section 2.3 or other state or federal requirements.

The following outlines what is needed to begin reporting to meet state and federal requirements. Once an agency has a CLIA Certificate or a CLIA Certificate of Waiver:

1. Register here: https://www.dshs.state.tx.us/coronavirus/forms/registerlab.aspx
2. Submit the online registration webform.
3. Complete DSHS onboarding process.
4. Submit required testing data to DSHS.

AND

1. Locate the local health entity or DSHS region for the area in which the parent agency is located: https://www.dshs.texas.gov/regions/2019-nCoV-Local-Health-Entities/
2. The local health entity or DSHS region will inform providers of any required reporting forms and processes.
3. The required data is submitted to the local health entity or DSHS region for the area in which the parent agency is located, using the forms and processes indicated.

DSHS is considering alternatives for registering and onboarding that would create a more simplified and streamlined method for uploading electronic lab results. Agencies that have made every attempt to register with DSHS, but are unable to complete registration, must keep all test-result documentation until the agency is able to submit the testing data. Once the agency successfully registers via the DSHS reporting system (or an alternative method created by DSHS), the agency will then submit all previous test result data.

Agencies can contact DSHS at: COVID-19ELR@dshs.texas.gov with any questions related to registration or reporting through DSHS.

3.0 Background / History

CMS began shipping POC antigen test kits to long term care providers with a CLIA Certificate or CLIA Certificate of Waiver in July 2020. A number of home health and hospice agencies have received testing kits. POC antigen tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs.

4.0 Resources

Federal Rapid Test Distribution for Largest 100 home health and hospice agencies

5.0 Contact Information

If you have any questions about this letter, please contact the Policy, Rules and Training Section by email at PolicyRulesTraining@hhsc.state.tx.us or call (512) 438-3161.