



Long-Term Care Regulatory Provider Letter

Number: PL 20-49 (Revised)

Title: Process to Request Free COVID-19 Point of Care Antigen Test Kits

Provider Types: Nursing Facility (NF), Assisted Living Facility (ALF), Intermediate Care Facility for Individuals with an Intellectual Disability or Related Conditions (ICF/IID), Home and Community-based Services (HCS) Program Provider, and Home and Community Support Services Agency (HCSSA)

Date Issued: November 23, 2020

1.0 Subject and Purpose

This provider letter has been revised to update the link for the BinaxNOW training for staff who will be administering the COVID-19 BinaxNOW tests. This letter describes the process to request distribution of a limited number of free BinaxNOW COVID-19 point of care (POC) antigen test kits under limited circumstances to certain NFs, ALFs, ICFs/IID, HCS program providers, and HCSSAs. The limitations in place are designed to help the Texas Health and Human Services Commission (HHSC) and the Texas Division of Emergency Management (TDEM) prioritize requests.

This initiative is new and unrelated to the antigen machines or the Centers for Medicare and Medicaid Services (CMS) distributions of BinaxNOW COVID-19 test kits.

2.0 Policy Details & Provider Responsibilities

To request consideration for the free BinaxNOW POC antigen COVID-19 test kits, an NF, ALF, ICF/IID, HCS program provider, or HCSSA must complete the Attestation for Free Test Kits ([LTCR Form 2198](#)) template applicable to the provider type. An NF, ALF, ICF/IID, or HCS program provider must submit the completed attestation to the HHSC Regional Director or designee for the region in which the provider is located. To request consideration for the free test kits for essential caregivers, an HCSSA must submit the

completed attestation to the HHSC Regional Director or designee in the region in which the inpatient hospice unit is located. To request consideration for the free test kits for HCSSA staff going into an NF or ALF, the HCSSA must submit the completed attestation to the HHSC Regional Director or designee where the NF or ALF is located.

The Regional Director or designee will elevate the completed attestation form to the State Operations Center in TDEM. Staff from HHSC Long-term Care Regulation (LTCR) and the TDEM will review the completed attestation form for accuracy and completeness. Staff may require and request documentation from the provider to support the attestation.

2.1 Eligibility

NF, ALF, ICF/IID, and HCS Program Provider Eligibility

The attestation criteria require an NF, ALF, ICF/IID, or HCS program provider to:

- be located in a county where the COVID-19 positivity rate is greater than 10% and in a rural area where there are limited free test sites available;
- have a current Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver or a CLIA laboratory certificate;
- only use the test kits to test essential caregivers;
- administer the test only by provider staff who successfully complete training provided by [Abbott Laboratories](#) or who are clinicians with appropriate education and training;
- follow all reporting requirements associated with the use of the Binax cards;
- report test results appropriately;
- not be part of a large corporation; and
- continue to seek out community resources to secure testing.

HCSSA Eligibility

The attestation criteria require an HCSSA to:

- have an inpatient hospice unit located in or provide services to individuals receiving hospices services in an NF or ALF located in:
 - a county where the COVID-19 positivity rate is greater than 10%, and
 - a rural area where there are limited free test sites available;
- have a current CLIA Certificate of Waiver or CLIA laboratory certificate;

- only use the test kits to test essential caregivers in the HCSSA's inpatient hospice unit and HCSSA staff going into NFs and ALFs who have direct contact with individuals receiving hospice services;
- administer the test only by HCSSA staff who successfully complete training provided by [Abbott Laboratories](#) or who are clinicians with appropriate education or training;
- follow all reporting requirements associated with the use of the Binax cards;
- report test results appropriately;
- not be part of a large corporation; and
- continue to seek out community resources to secure testing.

The term *essential caregiver* means a family member or other outside caregiver, including a friend, volunteer, private personal caregiver or court appointed guardian, who is at least 18 years old and has been properly designated to provide regular care and support to the client or resident.¹ The definition of *essential caregiver* does not include other persons providing critical assistance to the client or resident, such as contract doctors, clinical professionals, etc.

Typically, the term *large corporation* means 20 or more facilities or agencies in the State of Texas.

If a provider does not meet the free kit criteria in the attestation but would like to request consideration, the provider must describe the circumstances warranting consideration in the appropriate section of the attestation template. HHSC and TDEM will evaluate the request on a case-by-case basis.

2.2 CLIA Waivers

A provider must have a current CLIA Certificate of Waiver or a CLIA laboratory certificate before it can receive and administer the free BinaxNOW COVID-19 tests. To obtain a CLIA Certificate of Waiver for the free BinaxNOW COVID-19 tests, complete [Form CMS-116](#) available on the [CMS CLIA website](#) or on the [HHSC Health Care Facilities Regulation - Laboratories webpage](#) found under the Application header. Email the form to the regional CLIA licensing group via the [HHSC HCF Regulation – Laboratories webpage](#).

¹ The specific definitions for the term *essential caregiver* can be found at 40 TAC §19.2803(a)(5) for NFs, 26 TAC §553.2003(a)(5) for ALFs, 26 TAC §551.47(a)(5) for ICF/IIDs, 26 TAC §558.950(a)(5) for HCSSAs, and 40 TAC §9.199(b)(5) for HCS providers.

Providers that have existing CLIA Certificates of Waivers and are using a waived COVID-19 test are not required to update their CLIA Certificates 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.

For more specific guidance on the Certificate of Waiver application process, refer to HHSC COVID-19 provider letters and frequently asked questions (FAQs) applicable to the provider type.

2.3 Reporting COVID-19 Test Results

Providers performing the BinaxNOW COVID-19 testing authorized in this provider letter must report test results (positive, negative, or indeterminate) for each tested essential caregiver and tested HCSSA employee operating in an NF or ALF.

If an essential caregiver tests positive but is not allowed exposure to a resident or client, then the provider would not report it as exposure. The provider would still need to report the test results.

See provider letter 20-37, [Reporting Guidance for Long-term Care Providers](#), for reporting instructions.

For more specific guidance on the reporting requirements, refer to HHSC COVID-19 Texas Administrative Code rules, provider letters and FAQs applicable to the provider type.

3.0 Background/History

In October 2020, the State of Texas began receiving a limited supply of BinaxNOW COVID-19 POC antigen test kits to distribute to providers under limited circumstances.

4.0 Resources

[LTCR Form 2198, Attestation for Free Test Kits](#)

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.