



Long-Term Care Regulatory Provider Letter

Number: PL 2020-49 (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: March 25, 2021

1.0 Subject and Purpose

This provider letter has been revised to expand the availability of free BinaxNOW COVID-19 point of care (POC) antigen test kits. All long-term care providers can now request free BinaxNOW COVID-19 POC antigen test kits. The requested test kits can now be used to test any individuals, including residents, staff, and visitors. This letter describes the process to request distribution of a limited number of free BinaxNOW COVID-19 POC antigen test kits.

Providers can apply for BinaxNOW COVID-19 POC antigen test kits until supplies are exhausted.

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](#). 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, a 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

The attestation criteria require a NF, ALF, ICF/IID, HCS, and HCSSA program to:

- have a current Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver or a CLIA laboratory certificate;
- 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; and
- report test results appropriately.

Any provider that meets the requirements listed above is eligible to request free BinaxNOW COVID-19 POC antigen test kits.

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](#).

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 individual.**

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.

In March 2021, additional supplies of BinaxNOW COVID-19 POC antigen test kits allowed for the State of Texas to expand the eligibility for requesting free BinaxNOW COVID-19 POC antigen test kits.

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@hsc.state.tx.us or call (512) 438-3161.