

## DEPARTMENT OF SOCIAL AND HEALTH SERVICES

Aging and Long-Term Support Administration PO Box 45600, Olympia, Washington 98504-5600

December 15, 2020

ALTSA: ALF #2020-068
CLIA CERTIFICATE OF WAIVER

## Dear Administrator:

On December 2, 2020, providers were notified in <u>DPL 2020-059</u> that facilities administering point-of-care (POC) testing for COVID-19 must report all their COVID-19 testing results to the Department of Health (DOH) or Local Health Jurisdiction. In order to perform SARS-CoV-2 POC testing and report patient-specific results, a facility must be a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory or testing site that meets applicable regulatory requirements.

The Washington State Medical Test Site Program is temporarily exercising enforcement discretion under the state Medical Test Site (MTS) rules for SARS-CoV-2 Point of Care (POC) testing when a facility submits a <u>CLIA Certificate of Waiver (waiver) Medical Test Site application</u>, but has not yet been assigned a state medical test site license. Specifically, facilities that have received a federal CLIA number prior to being issued a state license can perform SARS-CoV-2 POC testing (as indicated on section 4 of the submitted CLIA waiver application) and report results as soon as they have been issued a CLIA number. A non-certified medical test site facility will be treated as operating under a CLIA waiver while their state license is being processed.

Facilities will need to email complete applications to <a href="lagocolor: lagocolor: white;">lagocolor: lagocolor: lagoc

Facilities that have submitted a CLIA waiver application should check with DOH before they begin testing as states may have additional licensure requirements that must be met before testing can begin.

For more information on how to apply for a CLIA waiver, use this link: <a href="https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/LaboratoryQuality">https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/LaboratoryQuality</a> Assurance/Licensing/Applications

For more information about reporting COVID-19 test results for POC testing facilities, use this link: <a href="https://www.doh.wa.gov/Emergencies/COVID19/HealthcareProviders/ReportingTestResults/ReportingCOVID19TestResultsforPointofCareTestingFacilities">https://www.doh.wa.gov/Emergencies/COVID19/HealthcareProviders/ReportingTestResults/ReportingCOVID19TestResultsforPointofCareTestingFacilities</a>.

Thank you for your continued commitment to resident health and safety. If you have any questions, please contact DOH Laboratory Quality Assurance at <a href="mailto:lga@doh.wa.gov">lga@doh.wa.gov</a> or 253-395-6746.

Sincerely,

Candace Goehring, Director Residential Care Services

DSHS: "Transforming Lives"