

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0622499	(X3) Date Survey Completed 02/03/2021
Name of Provider or Supplier West Linn Family Health Ctr Lab	Street Address, City, State 18380 Willamette Ste 202, West Linn, OR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on record reviews and interview with staff, the laboratory failed to report SARS-CoV-2 test results through the existing public health data reporting methods established by Oregon Health Authority. Findings Include: 1. Review of emails from Deputy Health Officer for the Tri County Health Officer Program, and the Clackamas County Health Department and West Linn Family Health Center revealed the laboratory had been performing SARS-CoV-2 tests and had not reported any test results until three clinic staff members tested positive on January 20, 2021 and January 21, 2021. 2. Review of the email dated January 21, 2021 reveals the Clackamas County Health Department nurse provided testing guidance and provided the link to the OHA COVID REPORTING PORTAL, the secure, web-based confidential reporting system, for the clinic to implement in order to report SARS-CoV-2 test results. 3. Interviews with both MA #1 and MA#2 revealed two Abbott ID NOW test systems were ordered and received in October 2020. It was further explained that at the time of the receipt of the instrument, MA #1 emailed to county requesting guidance what they needed to do. MA #1 was told by the county that they "did not need to report COVID test results". MA #1 was unable to find written</p>

documentation to support this statement. 4. The CLIA surveyor requested to view the laboratory policy procedure describing how SARS-CoV-2 test results are to be reported through the existing public health data reporting methods, the laboratory failed to produce one. 5. Interview with MA #1 and MA #2 confirmed that there was a total of 474 SARS-CoV-2 tests performed from October 13, 2020 to January 25, 2021 and were not reported to the County or to Oregon Health Authority. 6. Final interview during the onsite visit with clinic staff confirmed they were provided with the link to the OHA COVID REPORTING PORTAL, the secure, web-based confidential reporting system, by the county nurse. And they are currently working on implementing the OHA secure, web-based confidential reporting system. The interview with MA #1 and MA#2 concluded at 12:40 pm