

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0625696	(X3) Date Survey Completed 02/01/2021
Name of Provider or Supplier Downtown Salem Primary Care Lab	Street Address, City, State 1234 Commercial Street Se, Salem, 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 review of COVID 19 testing records and discussion with the Technical Consultant (TC), the laboratory failed to report all COVID antigen testing results. Findings include: 1. Upon review of the COVID 19 antigen testing procedure for this laboratory, it was noted that the procedure indicated that only positive results were to be reported to Marion County Public Health. 2. Upon review of the COVID 19 antigen test records for patients tested from December 01, 2020 through February 1, 2021, it was noted that in December 2020, only one (1) out of eight (8) COVID antigen patient tests performed were reported to Marion County Public Health. For the month of January 2021, it was noted that only two (2) out of twenty (20) COVID antigen patient tests performed were reported to Marion County Public Health. For February 1st, 2021, it was noted that two (2) out of two (2) patient test reports were not reported to Marion County Public Health. 3. During survey 02/01/2021 and interview with the TC at approximately 1 pm, she confirmed that the laboratory does not report the negative COVID antigen tests using Care Start COVID antigen test by Access Bio to Marion County Public Health.</p>

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and discussion with the Technical Supervisor (TS), the laboratory failed to ensure and follow written policies and procedures for the competency assessment of the TS were in place. Findings include: 1. During survey conducted 02/01/2021, no competency assessments for Hematology or Chemistry could be produced for the TS hired by the lab in August 2020. 2. The TS confirmed that she had had no competency assessment for Hematology or Chemistry by the Laboratory Director (LD) since her hire date in August 2020. 3. No written procedure for the competency of Technical Supervisor could be produced during survey 02/01/2021.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the COVID 19 Antigen testing procedure and interview with the Technical Consultant (TC), the laboratory failed to describe the method used to report all patient results. Findings include: 1. The procedure for reporting COVID 19 Antigen testing does not include the method by which the laboratory will report the results to county public health authorities. 2. The procedure for reporting COVID 19 Antigen testing does not include reporting of negative test results to the county public health authorities. 3. The TC confirmed that negative results are not currently reported to the county public health authorities as of February 1, 2021.