

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  38D0679715	<b>(X3) Date Survey Completed</b>  03/14/2024
<b>Name of Provider or Supplier</b>  Salem Clinic Laboratory	<b>Street Address, City, State</b>  2020 Capitol Street Ne, Salem, OR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency records, and interview with the General Supervisor (GS)/Technical Supervisor (TS), the laboratory failed to have policies in place to assess the GS and TS competency. Findings include: 1. Review of competency records for 2023 and 2024 revealed the laboratory did not have a policy in place and did not perform competency for the GS and TS. 2. Interview with the GS/TS confirmed these findings on 03/14/2024 at 14:00 pm in the laboratory office. 3. The laboratory performs 1,366,746 tests annually.</p>
<b>D5807</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the approved normal values in the laboratory procedure manual, review of patient report, and interview with the Technical Supervisor (TS), the laboratory failed to ensure the test report included pertinent normal ranges as determined by the laboratory. Ten (10) out of fourteen (14) chemistry normal values and six (6) out of twenty-two (22) listed on the laboratory information system (LIS)</p>

report differed from those in the approved procedure manual. Findings include: 1. Review of patient report 1803950 from the LIS system revealed the following. LIS Patient Report Procedure Manual Chemistry: Alanine Amino transferase 7.0 - 42 u/L 10 - 49 u/L Albumin 3.3 - 4.9 G/DL 3.2 - 4.8 G/DL Total Protein 5.8 - 8.5 G/DL 5.7 - 8.2 G/DL Total Bilirubin 0.2 - 1.2 MG/DL 0.3 - 1.2 MG/DL Glucose 69 - 100 MG /DL 74 - 106 MG/DL Creatinine 0.30 - 1.1 MG/DL 0.50 -1.3 MG/DL Urea Nitrogen 5 - 21 MG/DL 9.0 - 23 MG/DL Carbon Dioxide 23.8 - 32.8 mEq/L 20 - 31 mEq/L Chloride 97 -110 mEq/L 99- - 109 mEq/L Potassium 3.4 - 4.8 mEq/L 3.5 - 5.5 mEq/L Hematology: Hemoglobin 12.4 - 15.5 G/DL 11.8 - 15.5 G/DL Mean Cell Volume 84. - 99.8 fL 81.5 - 100.5 fL Mean Corpuscular Hemoglobin 26.9 - 32.6 fL 26.1 - 33.3 fL Neutrophils # 1.9 - 6.63 10\*3/uL 1.39 - 6.69 10\*3/uL Lymphocyte # 1.03 - 2.82 10\*3 /uL 0.84 - 3.08 10\*3/uL Basophils # 0.01 - 0.07 10\*3/uL 0.00 - 0.08 10\*3/uL 2. Interview with the TS confirmed the laboratory failed to ensure correct references ranges approved in the procedure manual were the same as in the LIS patient reports on 03/14/2024 at 14:00 pm in the laboratory office. 3. The laboratory performs 1,048,442 chemistry tests and 244,561 hematology tests annually.