

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0679715	(X3) Date Survey Completed 03/04/2026
Name of Provider or Supplier Salem Clinic Laboratory	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 the CMS-209 form, laboratory procedures, training and competency assessment (CA) records and an interview with the technical supervisor (TS), the laboratory failed to follow written policies and procedures to assess moderate complexity testing personnel (TP) in 2024. Findings include: 1. The CMS-209 form identified thirteen (13) TP performing moderate complexity testing. 2. Review of the Laboratory Personnel Competency Assessment Policy states all TP competency assessments must occur annually. 3. A review of CA records identified that the TC failed to perform a CA for all moderate complexity TP in 2024. 4. Interview with the TS #1 at 10:00am on 03/04/2026 confirmed the above findings. 5. The laboratory performs 204 moderate complexity microscopy tests annually.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory procedures, maintenance records and an interview with the technical supervisor (TS), the laboratory failed to follow written policies and procedures to perform centrifuge maintenance. Findings include: 1. Upon requesting documentation of centrifuge maintenance for 2024 and 2025, none could be produced. 2. Interview with TS #1 at 12:00pm on 03/04/2026 confirmed there were no maintenance documents for the centrifuge.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures and interview with the Technical Supervisor (TS), the laboratory failed to define and implement a procedure to evaluate testing when the same analyte is tested on different instruments twice a year. Findings include: 1. Upon requesting written documentation of test comparison results for 2024 and 2025 for the two Sysmex XN hematology instruments, none could be produced. 2. The laboratory did not have a procedure to evaluate comparison of test results for analytes that are tested on multiple instruments. 3. Interview with TS #3 at 11:00 am on 03/04/2026 confirmed there was no policy on comparison of test results for analytes that are tested on multiple instruments. 4. The laboratory performs 244,046 hematology tests annually.