

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 50D0637505	(X3) Date Survey Completed 02/13/2024
Name of Provider or Supplier Kaiser Permanente Longview	Street Address, City, State 1230 7th Ave, Longview, WA	
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 a review of the laboratory policies and procedures, testing personnel (TP) competency records, and interviews with the laboratory Technical Supervisor (TS), the laboratory failed to follow established written policies and procedures to assess employee TP and consultant competency. Findings include: 1. A review of the laboratory submitted Form CMS-209 identified seven (7) TP-performing Point of Care (POCT) Provider performed microscopy (PPM) testing. 2. The laboratory's Competency Assessment Procedure, approved on 12/26/2023 (page 11), identifies "Non-Waived: Tests categorized as either moderate or high complexity (including provider-performed microscopy).. the laboratory is required to have competency assessments assigned to non-waived TP through its Media Lab program twice annually. 3. A review of the laboratory's Media Lab program records revealed that three (3) of seven (7) PPM TP had not performed their assigned competency assessments for 2023, and four (4) of seven (7) TP had not performed their assigned competency assessments in 2022. 4. The laboratory TS confirmed, by interview on 12/13/2024 at 13:30 p.m., that the assigned competency testing for PPM POCT TP had not been completed.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification</p>

procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's maintenance records and interview with the Technical Supervisor (TS) and the General Supervisor (GS), the laboratory failed to document calibration verification after the manufacturer preventive maintenance (PM) was performed. Findings include: 1 The laboratory maintenance records for the Sysmex XN Hematology analyzer listed a PM performed by the manufacturer's field technician on 11/16/2023. 2. A request for the post PM calibration records revealed a lack of documentation of a calibration reresults or report performed by the field technician, or the laboratory staff following the PM maintenance on the XN Hematology analyzer. 3. The laboratory GS confirmed, in an interview on 02/13/2024 at 1:45 p.m., the lack of documentation for the calibration record after PM was performed. 4. The laboratory reports performing 36722 Hematology tests annually.