Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0217205	05/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Kaiser Permanente-Woodlawn Laboratory	7141 Security Blvd, Woodlawn, MD	

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
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) (a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on procedure manual and quality assurance (QA) record review, and interview with the laboratory manager (LM), the laboratory failed to retain all hematology quality system assessment records for at least two years. Findings: 1. The laboratory manages and evaluates their hematology quality control (QC) by using the manufacturer's "Insight Quality Assurance Program (QAP)" which compares their QC results to a peer group for each lot number (#) of QC. 2. The procedure, "Sysmex XN-1000 and XN-2000 Procedure" states that the laboratory should print and save QC data to "removable media" and that the "CV [Coefficient of Variation] must be reviewed and any changes in CV must be documented with investigation if needed." 3. Record review showed that the laboratory printed "Sysmex Insight" "XN Check" "Lot-to-Date" reports for the different lot # of hematology QC run on the Sysmex hematology analyzer. The reports were reviewed and signed by the LM. 4. A review of Sysmex Insight reports from May 2024 through January 2025 showed that the "Lot-to-Date" report for lot # 4115 included the three levels of hematology QC run from 05/09/2024 through 05/31/2024. The next available "Lot-to-Date" report was for lot # 4171 and included the three levels of hematology QC run from 07/05/2024 through 09/03/2024. There was no documentation that the laboratory had evaluated the hematology QC run between 06/01/2024 and 07/04/2024; and 5. The "Lot-to-Date" report for lot # 4227 included the three levels of hematology QC run from 08/27/2024 through 10/31/2024. The next available "Lot-to-Date" report was for lot # 4339 and included the three levels of hematology QC run from 12/12/2024 through 01/02/2025. There was no documentation that the laboratory had evaluated the hematology QC run between 11/01/2024 and 12/11/2024. 6. During an interview on 05/12/2025 at 6:20

	PM, the LM confirmed that the laboratory failed to maintain all hematology QA records for a minimum of two years.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) procedure, review of PT records, and interview with the quality technical specialist (QTS), the laboratory failed to perform a self-evaluation or failed to document an investigation and corrective action for discrepant results for PT samples that were not graded by the PT provider in 5 of 15 PT events reviewed for 2023. Findings: 1. The laboratory was enrolled in PT with the College of American Pathologists (CAP). 2. The CAP's participant summary included a section titled "Actions Laboratories Should Take when a PT Result is Not Graded" that included the following instructions for exception codes: a. [11] Unable to analyze: Document why the specimens were not analyzed (eg, instrument not functioning or reagents not available). Perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested. b. [26] Educational challenge: Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation. 3. The laboratory's "Proficiency Testing" procedure stated: a. "6.6.9 If the survey results are unacceptable: 6.6.9.1 The laboratory Manager will initiate a full investigation of the unacceptable results using the Survey Exception Investigation: FORM." b. "6.7 If the survey results are ungraded:" i. "6.7.1.2 Compare the Laboratory's results with the survey material results and document any reason(s), discrepancies, or non-discrepancies on the evaluation report." ii. "6.7.1.2.1 For discrepant and non- discrepant results document the statement of the percentage of agreement. Any agreement less than 100% will require a survey exception to be completed." iii. "6.7.1.2.3 For educational challenges, explain any disagreements with the survey material results." 4. For the C-A 2023 General Chemistry/Therapeutic Drugs event: a. None of the chemistry analytes were graded by CAP with the exception code [11]. b. The evaluation report included the note "Kit not received from CAP" and was signed by the laboratory director on 06/13/2023. c. There was no documentation of an investigation into why the kit was not received and no documentation that replacement samples were evaluated or an alternative assessment was performed for that period as recommended by CAP and to ensure that the regulated analytes were challenged at least three times in 2023. 5. For the CGL-A 2023 Coagulation, Limited event: a. The results for D-dimer, quant were 0%. The evaluation stated "D-dimer results are unacceptable. To investigate and submit corrective action to QA and medical director." There was no documentation of an investigation into the unacceptable D-dimer results. b. The samples for Activated PTT, qual were not graded by CAP with the exception code [26]. There was no documentation that the laboratory's results were compared with CAP's participant summary. 6. For the FH9-A 2023 Hematology Auto Differentials event: a. The results for IG; IG Absolute; nRBC%; nRBC%, absolute; and Immature Platelet Frac % were not graded by CAP with the exception code [26]. b. There was no documentation that

	the laboratory's results were compared with CAP's participant summary. 7. For the KP-A 2023 Blood Cell Identification, Photographs event: a. Sample BCP-08 was self-evaluated as 69% for Neutrophil, myelocyte. b. The participant summary showed that the result for Neutrophil, myelocyte was actually 13.2 % of referee labs while Neutrophil, promyelocyte was 68.3%. c. There was no documentation of an investigation into the discrepant results. 8. For the FH9-C 2023 Hematology Auto Differentials event: a. Sample BCP-27 was self-evaluated as 6% for Neutrophil, giant band and "97% = Mono" was written on the evaluation report. b. The participant summary showed that the top result was Monocyte identified by 54.5% of referee labs (97 labs). c. There was no documentation that a survey exception form was completed as stated in the procedure. 9. During the survey on 05/12/2025 at 1:15 PM, the QTS confirmed that there were ungraded PT samples that were either not self-evaluated or there was no documentation of an investigation and corrective action for discrepant results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on procedure manual, patient log, and quality assurance (QA) record review and interview with the laboratory manager (LM), the laboratory failed to follow written procedures for performing data entry verifications of patient test results as part of the QA program. Findings: 1. The procedure, "Verification of Test Data" states that daily the laboratory "will review LIS [laboratory information system] results of 10% of the laboratory tests on each worksheet to verify that the instrument printouts or manual logs and the results that have been entered in the LIS are the same" and that "the number of results checked will be recorded on the appropriate Result Check Log." 2. The laboratory fills out a monthly "Verification of Test Results" log (verification log) to document the verification of 10% of entered test results for "CBC /Diff," "COAG," "CHEM," "UR/Micro," "Pregnancy," "Rapid Strep," "OSOM BV," and "OSOM TV." A review of verification logs from January 2024 and January 2025 showed that the test result reviews were documented with a check mark. The logs did not show the number of patient results checked as stated in the procedure manual. 3. A review of the verification log from January 2024 also showed that verification checks were not documented for "Pregnancy" or "Rapid Strep" for 01/02/2024 through 01/05/2024. A review of manual patient logs showed that "Pregnancy" tests were performed on two patients on 01/02/2024; four patients on 01/03/2024; four patients on 01/04/2024; and eight patients on 01/05/2024; and 4. "Rapid Strep" tests were performed on six patients on 01/02/2024; five patients on 01/03/2024; two patients on 01/04/2024; and four patients on 01/05/2024. 5. Record review also showed that no verification checks were documented for any of the testing categories on 01/30/2024 and 01/31/2024 (two out of 21 days of testing). 6. The daily patient log worksheets for "Pregnancy" and "Rapid Strep" testing has a spot on the bottom of each where the person reviewing the sheet and the date should be documented. During an interview on 05/12/2025 at 11:50 AM, the LM stated that the sheet should be signed by the person performing the 10% verification procedure. 7. A review of daily "Pregnancy" and "Rapid Strep" patient logs from January 2024 showed that the logs

	were not signed by the reviewer for 21 of 21 days of testing. 8. During an interview on 05/12/2025 at 6:20 PM, the LM confirmed that the laboratory failed to follow written procedures for data entry verification of patient test results as part of their QA program.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on deionized (DI) water quality control log record review and interview with the laboratory manager (LM), the laboratory failed to document monthly bacterial culture checks to ensure accurate and reliable test system operation, and test result reporting. Findings: 1. The laboratory employs a filtration system to supply DI water for its operations. The laboratory documents daily and monthly quality checks on the "DI Water System Quality Control Monitoring Log" (DI QC log). 2. Once a month the laboratory collects a DI water sample to send out for culture, to ensure that there is no bacterial contamination in the DI water system. The monthly DI QC log includes a space to document the "Monthly Bacterial Content Check" as "Pass/Fail." 3. A review of DI QC logs from January through June 2024 showed that the result of the monthly bacterial culture was not documented for three of six months. 4. During an interview on 05/12/2025 at 6:20 PM, the LM confirmed that the laboratory failed to document monthly DI water culture results to ensure that the DI water used in the laboratory was free of bacterial contamination.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on instrument maintenance record review and interview with laboratory manager (LM), the laboratory failed to ensure that weekly maintenance was performed on the Stago "STA Compact Max" coagulation analyzer with at least the frequency specified by the manufacturer. Findings: 1. The laboratory uses a Stago "STA Compact Max" coagulation analyzer to perform coagulation testing. The "STA Compact Max Maintenance Chart" lists nine tasks which must be done as part of the weekly maintenance. 2. A review of monthly "STA Compact Max Maintenance Charts" from January through December 2024 showed that weekly maintenance was documented two weeks out of the month for seven of 12 months, and three weeks out

	of the month for one of 12 months. 3. During an interview on 05/12/2025 at 6:20 PM, the LM confirmed that weekly coagulation analyzer maintenance was not performed and documented as recommended by the manufacturer.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the procedure and monthly quality assessment (QA) reports and interview with the quality technical specialist (QTS), the laboratory director failed to ensure that the monthly QA reports were completed as stated in the procedure. Findings: 1. The "Monthly Quality Monitors" procedure stated: a. "1.1 This procedure is to ensure the KPMAS laboratories utilize the monthly quality monitor calendar and report to document continual assessment of the Quality Management Plan." b. "6.1.3.2.1 The QA Monitors report is completed a month behind and is to be completed, signed, and filed by the end of said month." c. "6.1.3.2.1.1 For example: January will be completed in February when all the data is available for documentation. The Monitor with January information will be printed, reviewed, signed, and filed by the end of February." 2. The laboratory documented the indicator results on the "Quality Indicator Report" spreadsheet (QA report) which was printed, reviewed, and signed monthly. 3. The QA reports from 03/2023-12/2024 were reviewed. 4. Monthly printed QA reports from 11/2023-03/2024 were missing. 5. The printed monthly QA report from 11/2024 was not signed as reviewed. 6. The QTS stated that the frequency for each task was indicated by a white cell on the spreadsheet. Tasks that were not scheduled for any given month were gray. 7. The 2023 QA report showed that tasks for 11/2023 and 12/2023 were not performed. 8. Linearity for the Integra was performed once in 2023. The second linearity scheduled for 11/2023 was not documented on the QA report. 9. Linearity for the Stago, Triage, and Integra was performed once in 2024. The second linearities scheduled for 10/2024 and 12/2024 were not documented on the QA report. 10. The 2024 QA report had blank white cells (indicating that scheduled activities were not performed) under the Administrative, Comparison/Correlation, LIS/Quality, Staff Competencies, and Safety and Customer Feedback sections. 11. During the survey on 05/12/2025 at 4:30 PM, the QTS confirmed that the printed monthly QA reports were missing from 11/2023-03/2024 and that scheduled activities were not documented as performed on the reviewed 2023 and 2024 QA reports.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the quality technical

	specialist (QTS), the competency assessments for two of two testing personnel (TP) were self-performed in 2023. Findings: 1. The competency assessment forms included an "Assessor" column that captured the initials of the person who performed the competency evaluation. 2. The laboratory listed two TP on the Laboratory Personnel Report (form CMS-209). 3. The initials of the "Assessor" on the 2023 competency assessment forms matched the names of the TP being assessed. 4. During the survey on 05/12/2025 at 4:00 PM, the QTS confirmed that the initials listed in the "Assessor" column were from the TP who were being assessed indicating that the TP performed a self-evaluation for their own competency.