Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0260210	12/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Kaiser Permanente Cumberland Laboratory	2525 Cumberland Parkway, Atlanta, GA	

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
D0000	A recertification survey was performed on December 13, 2023.previous to the survey. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties/subspecialties for 42 CFR.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing reports and TC interview, the laboratory failed to review and evaluate performance on all PT reports received. Findings: 1. Review of PT reports for 2022 events 2 &3 and 2023 events 1, 2 , & 3 revealed the lab did not review results for 2023 event 2. 2. Interview with the TC (CMS 209) on 12/13/23 in the lab area outside the TC's office at 11:45 am, confirmed the lack of PT review (2023 event 2).
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the lack of Quality Assessment (QA) documents and interview with the TC,

	the laboratory failed to verify the accuracy of the QA system. Findings : 1. Review of the laboratory's records revealed no documentation of QA monitors were being performed. 2. Interview with the TC (CMS 209), on 12/13/23, at 12:50 pm, in the lab area outside the TC's office, confirmed the laboratory lacked documentation of QA monitors being performed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Sysmex XN450 analyzer installation data and interview with the TC, the LD failed to approve the data prior to use of the analyzer. Findings: 1. Review of the Sysmex XN450 analyzer installation data performed August 2022-September 2022 disclosed the lack of an approval signature by the LD. 2. Interview with the TC on 12/13/23 at 11:31 am in the lab area outside the TC's office, confirmed the lack of the LD's approval signature.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records and TC interview, the laboratory director (LD) failed to ensure all testing personnel had performance/competency evaluated annually. Findings: 1. Review of TP records for 2022-2023 revealed the LD did not perform competency evaluation on TP#3 (CMS 209 form). 2. Interview with the TC (CMS 209 form) on 12/13/23 at 11:00 AM in the lab area outside the TC's office, confirmed the LD failed to ensure TP#3 (CMS 209) had performance /competency evaluated annually.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on standard operations procedure manuals (SOPs) review and interviews with the technical consultant (TC) and the lab director (LD), the LD failed to approve the SOPs as required. Findings: 1. Review of the lab's SOPs revealed the the lack of the LD's approval of the laboratory SOPs. 2. Interview with the TC and LD in a lab area outside the TC's office on 12/13/23 at 11:30 a.m. confirmed the lack of the LD's approval of the laboratory SOPs.