Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0260210	01/24/2019
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 24, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
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 Sysmex hematology instrument document review and staff interview, the laboratory failed perform a validation study as required. Findings include: 1. Sysmex hematology analyzer document review revealed a validation study was not performed on a loaner Sysmex hematology analyzer put into use in this facility on 1/18/19. 2. An interview with the Technical Consultant in the laboratory on 1/24/18 at approximately 4 p.m confirmed a validation study was not performed on the Sysmex hematology analyzer in use in this facility at the time of survey.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for

	sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on bacteriology quality control (QC) document review and staff interview, the laboratory failed to performed required QC on bacteriology media. Findings include: 1. Bacteriology QC document review revealed the laboratory failed to perform sterility checks for the following: UR Cled media - 2017; DTM media -- 2017, 2018, and 2019 thus far. 2. Bacteriology QC document review revealed the laboratory failed to perform QC for the following: UR Cled media and DTM media -- 2017, 2018, and 2019 thus far. 3. An interview with the technical consultant on 1/24/18 in the laboratory at approximately 4:00 p.m. confirmed the aforementioned failures to perform media QC.
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 personnel document review and staff interview, the laboratory director (LD) failed to designate in writing the individual responsible for performing technical consultant (TC) competencies. Findings include: 1. Personnel document review revealed there was no designee letter from the LD to delegate responsibility of TC competency performance in 2018.. 2. An interview with the TC in the laboratory on 1 /24/18 at approximately 4:00 p.m. confirmed there was not a designee letter for the individual who performed her six-month competency in 2018.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of

	Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory failed to employ qualified TP due to lack of required education documentation. =[Findings include: 1. TP document review revealed Staff #4 (CMS 209) was unqualified to perform laboratory testing due to lack of an equivalency letter for her foreign college degree. 2. An interview with the TC on 1/24/18 in the laboratory at approximately 4:00 p.m. confirmed there was no equivalency letter for a foreign college degree for Staff #4 (CMS 209).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure that all TP have the appropriate training for the type and complexity of the services offered as required. Findings include: 1. TP document review revealed Staff #2 (CMS 209) did not have an initial training competency performed in 2018. 2. An interview with the technical consultant in the laboratory at approximately 4 p.m. on 1/24/18 confirmed an initial competency was not performed on Staff #2 (CMS 209) in 2018.