Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0711632	01/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kaiser Permanente Panola Laboratory	5440 Hillandale Drive, Lithonia, 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) reinstatement survey was completed on January 17, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on calibration document review and staff interview, the laboratory failed to perform instrument calibrations with the frequency required. Findings include: 1. Sysmex hematology analyzer calibration document review revealed the laboratory failed to perform a calibration every six months in 2017. There was a calibration gap between 9/19/16 and 12/15/17. 2. An interview with Staff #1 (CMS 209) in the laboratory on 1/25/18 at approximately 2:00 p.m. confirmed the hematology analyzer calibrations were only done once in 2017.
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 microbiology quality control (QC) document review and staff interview, the laboratory failed to perform a bacteriology media sterility check as required. Findings include: 1. Microbiology QC document review revealed the laboratory failed to perform a sterility check for each batch of media for 2016, 2017, and 2018 thus far. 2. An interview with Staff #1 (CMS 209) in the laboratory on 1/25/18 at approximately 2:00 p.m. confirmed bacteriology media sterility checks were not performed for 2016, 2017, and 2018 thus far.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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 each TP receive proper training as required. Findings include: 1. TP document review revealed there was no documentation of an initial training competency performed for Staff #1 (CMS 209) in 2016. 2. An interview with Staff #1 (CMS 209) confirmed there was no initial training competency performed for Staff #1 (CMS 209) in 2016.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) reports and staff interview, the laboratory director (LD) failed to ensure an approved correction plan was followed when any PT result was found to be unsatisfactory. Findings include: 1. College of American Pathologists (CAP) PT report review revealed for 2016 Event 3 (Prothrombin Time of 60 percent), no corrective action was performed. 2. An interview with the General

	Supervisor in the laboratory on 1/25/18 at approximately 1:30 p.m. confirmed no corrective action was performed for the aforementioned unsatisfactory PT result.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical supervisor (TS) failed to ensure a six-month evaluation was performed on individuals responsible for high-complexity testing during the first year the individual tested patient specimens. Findings include: 1. TP document review revealed a six-month competency was not performed for Staff #1 (CMS 209) in 2016. 2. An interview with Staff #1 (CMS 209) in the laboratory on 1/25/18 at approximately 2:00 p.m. confirmed a semi-annual competency was not performed for Staff #1 (CMS 209) in 2016.