Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1008967	11/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kaiser Permanente, Tspmg Brookwood Laboratory	1745 Peachtree Street Nw, Ste U, 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 November 26, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) documents review and staff interview, the laboratory failed to monitor over time the accuracy and precision of test performance as required. Findings include: 1. QC document review revealed there were no Levey Jennings charts available for 2017 (August through December), 2018,and 2019 thus far. 2. An interview with Staff #2 (CMS 209) in a medical office on 11/26/2019 at approximately 1:45 p.m. confirmed the lack of Levey Jennings charts for the aforementioned time periods.
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 all TP have the appropriate training prior to testing patients' specimens as required. Findings include: 1. TP competency document review revealed the lack of 2018 initial training documents for Staff #1 (CMS 209). 2. An interview with Staff #2 on 11/26/2019 at approximately 1:45 p.m. in a medical office confirmed the aforementioned lack of competency performance.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory director (LD) failed to specify in writing the responsibilities and duties of each person engaged in the performance of all phases of laboratory testing as required. Findings include: 1. SOP review revealed the lack of a duties and responsibilities policy and procedure. 1. An interview with Staff #2 (CMS 209) in a medical office on 11/26/2019 at approximately 1:30 p.m. confirmed there was not a duties and responsibilities policy in the SOP.