Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D2114331	09/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kaiser Permanente Capitol Hill Med Cntr Cdu Lab	700 2nd Street Ne, Washington, DC	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab did not have attestation statements for the second proficiency test event of 2018 for troponin (cardiac kit), and the second proficiency test event of 2018 for lactic acid (blood gas kit). Findings: 1. The lab enrolls in proficiency testing with an approved proficiency test provider, and three times a year during enrollment, the provider mails the lab five samples (these samples are unknowns and the concentration of the analytes is not provided to the lab). The lab performs the tests and submits the results to the provider to evaluate for accuracy. Prior to testing, the lab director and the testing staff must sign an attestation statement that the proficiency test samples are tested in the same manner as patient samples; 2. In 2018 the lab did not have records showing that the analyst signed attestation statements for the troponin and lactic acid tests for the second events in 2018; and 3. This was confirmed during interview with lab staff on the day of survey.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty,

	subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency test records and interview with staff, the laboratory (lab) performed unsuccessfully on proficiency testing for lactic acid and troponin in 2019. See D2096 for findings.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's proficiency testing performance was unsuccessful for both troponin and lactic acid in 2019. Findings: 1. The laboratory obtained a score of 0% on proficiency testing for lactic acid (blood gas kit) on the 3rd event in 2018 and the 1st event in 2019; 2. The laboratory obtained a score of 0% on proficiency testing for troponin (cardiac kit) on the 1st and 2nd events in 2019; 3. During interview with lab staff, it was determined that the lab did not receive the proficiency test kits from the receiving department at their facility and obtained scores of 0% due to the fact that the proficiency testing was not performed; and 4. At the time of the survey, the lab has not implemented corrective actions to ensure that the proficiency test kits are identified and brought to the lab within acceptable time limits.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab did not have records showing that the lab director evaluated the competency of the technical consultant for duties performed as technical consultant. Findings: 1. Technical consultant # 1 is identified as the technical consultant for the laboratory on the CMS form- 209; 2. The lab did not have records to show that the lab director performed

	competency checks for Technical Consultant # 1 in performance of duties and responsibilities as technical consultant; and 3. This was confirmed during interview with lab staff on the day of survey.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab's written standard operating procedures for chemistry testing did not include instructions for the total testing process. Findings: 1. The written procedure for troponin and lactic acid assays did not include the reportable range for each test (established during the lab's validation of each test); 2. The written procedure for troponin and lactic acid assays did not include the normal patient reference ranges (established during the lab's validation of each test); 3. The written procedure for troponin and lactic acid assays did not include critical care results for troponin and lactic acid assays and did not include procedures for notifying the clinician (if appropriate); 4. The written procedure for troponin and lactic acid assays did not include the instructions to identify the patient at the time of venous or capillary blood collection, and instructions for labeling of patient specimens to ensure their positive identification; and 5. The findings were confirmed during interview with lab staff on day of survey.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the current lab director did not sign the standard operating procedures showing the directors review and approval of the chemistry written procedures. This was confirmed with lab staff during interview on the day of survey.

D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on interview with laboratory (lab) staff, the lab did not have policies and written procedures to issue corrected reports when test results are entered directly into the clinical or user information system. Findings; 1. Testing persons enter troponin and lactic acid patient test results directly into the clinical record (information system); 2. The lab does not have written procedures to correct lab results that are reported incorrectly when entered directly into the clinical information system; 3. There was no written procedure to identify an incorrect test result as incorrect; 4. There was no written procedure to notify the user of the correct test result, when an incorrect test result was previously reported; and 5. This was confirmed during interview with staff on the day of survey.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review, the laboratory's proficiency test performance was unsuccessful for both troponin and lactic acid in 2019 (see D2096); and the laboratory director did not provide a corrective action plan for the unsuccessful performance (see D6019).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory director did not provide a written corrective action plan when the laboratory's proficiency testing performance was unsuccessful for both troponin and lactic acid in 2019. Findings: 1. The laboratory obtained a score of 0% on proficiency testing for lactic acid (blood gas

	kit) on the 3rd event in 2018 and the 1st event in 2019; 2. The laboratory obtained a score of 0% on proficiency testing for troponin (cardiac kit) on the 1st and 2nd events in 2019; 3. During interview with lab staff, it was determined that the lab did not receive the proficiency test kits from the receiving department at their facility and obtained scores of 0% due to the fact that the proficiency testing was not performed; and 4. At the time of the survey, the lab has not implemented corrective actions to ensure that the proficiency test kits are identified and brought to the lab within acceptable time limits.
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 record review and interview with laboratory (lab) staff, the lab did not have duties and responsibility statements for each employee and position held. Findings: 1. The written procedure did not include duties and responsibility statements for each employee, including lab director, clinical consultant, technical consultant and testing persons; and 2. This was confirmed during interview with staff on the day of survey.