Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0709721	07/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Patients Hospital Of Redding	2900 Eureka Way, Redding, CA	

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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: . Based on observation of the Horiba ABX Micros 60 hematology analyzer in the laboratory, review of proficiency testing (PT) reports for 2023, Event 2, from API (American Proficiency Institute) and CMS (report 155, Individual Laboratory Profile) and laboratory proficiency testing records; and interview with Technical Consultant /Testing person-1, it was revealed that the laboratory failed to attain a score of at least 80% for RBC (Red Blood Cell Count). Findings included: a. CMS and API reported the score of 40% due to the laboratory's 3 unacceptable results (*) out of 5, as follows: PT sample ID Reported Acceptable ---------- HEM-06 4.39 * 3.80 - 4.29 HEM-07 5.38 * 4.75 - 5.37 HEM-09 5.40 * 4.73 - 5.35 b. Technical Consultant/Testing person -1 affirmed (7/24/24 at 11:30 AM) the aforementioned unacceptable results and score constituting unsatisfactory testing for RBC; and that the results for the remaining two PT samples were acceptable but on the high side. c. The quality and reliability of the Horiba to provide accurate RBC results during the timeframe April - August 2023 could not be assured. . .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as

	acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on observation of the EPOC analyzer, review of 2023 - 2024 laboratory test records, the lack of records, and interview with the Technical Consultant/Testing person-1, it was determined the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings included: a. The laboratory used Siemens EPOC analyzer, serial number 47134, to test for 10 analytes, as follows: Sodium Glucose Potassium BUN Calcium Creatinine Chloride BUN/Creatinine CO2 (calculated) Hematocrit b. Records documented EPOC calibration and calibration verification performed on 5/30/23 and 2/14/24. c. The Technical Consultant/Testing person-1 affirmed (7/24/24 at 6:00 pm) the laboratory failed to calibrate and verify calibrations within 6 months of 5/30/24, by 11/30/23. d. Review of patients test records for the timeframe 11/30/24 to 2/13/24 revealed 39 patient specimen had each been tested for 10 analytes and reported. The quality and reliability of 390 out of 390 results reported could not be assured, when the EPOC had not been calibrated and calibrations verified. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation of the Siemens EPOC analyzer, review of 2024 EPOC laboratory test records, the lack of QC results, and interview with Technical Consultant/Testing person-1, it was determined the laboratory testing personnel failed to include two quality control materials of different values each day of testing patient specimens and failed to have an IQCP (Individualized Quality Control Plan). Findings included: a. The laboratory had a Siemens EPOC analyzer to test for chemistry analytes and hematocrit, as follows: Sodium Glucose Potassium BUN Calcium Creatinine Chloride BUN/Creatinine CO2 (calculated) Hematocrit b. Review of patients' test records for 2023 - 2024 revealed no records documenting QC performance, as follows: Date ID QC ---------- 4/26/24 32573

	none 7/23/24 32697 none c. The laboratory Technical Consultant /Testing person-1 affirmed (7/24/24 at 5:30 pm) that the laboratory implemented the practice of performing QC on a weekly basis instead of each day of testing, effective April 2024. d. The laboratory failed to provide for review the IQCP document establishing a customized QC plan for the EPOC test method and use, including required components, as follows: 1. Risk Assessments evaluating the potential for errors from five sources: i. Specimen, ii. the Test System, iii. Reagents, iv. the Testing Environment, and v. Testing personnel. 2. The Quality Control Plan establishing type and frequency of quality control materials based on analysis of historical consecutive days of QC data; 3. Quality Assessment processes for monitoring quality and detecting errors when QC is not performed each day of patient testing. e. The Technical Consultant/Testing person-1 affirmed (7/24/24 at 5:30 pm) the aforementioned lack of IQCP document. d. The quality and reliability of EPOC test results could not be assured for the timeframe beginning April 2024 to present, when QC was not performed with each day of testing and the IQCP had not been documented and approved for implementation. .
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on the deficiency cited at D5447, the Laboratory Director is herein cited for deficient practice in ensuring the quality control program is maintained or that the IQCP is established to assure the quality of testing. Findings included: a. The Laboratory Director had no process for overseeing, reviewing, or approving the IQCP for the EPOC.