Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2221797	11/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Adventhealth Imaging Center Roeland Park	5675 Roe Blvd, Suite 120, Roeland Park, KS	

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
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 upon a review of the laboratory procedures and interview with the laboratory director (LD), the laboratory failed to define by written procedure: instruction for entering results in the patient record and control procedures for creatinine testing on the epoc blood analysis system. Findings: 1. The procedure "epoc(R) Blood Analysis System Standard Operation Procedure" contained no section on reporting results and no information on how to enter the test results into the patient record. 2. In interview with the testing personnel # 2 (TP2) on 11/1/21 at 11:30 a.m. about how patient results are reported, TP2 stated only the values are entered into the immaging module

	of their electronic medical record which does not include units of measure or reference intervals. 3. In the procedure section "Quality Control (QC)" the following statement under "Liquid QC" read "No daily liquid QC is required for the epoc(R) system as long as an Individualized Quality Control Plan (IQCP) is in effect for the system." No interval for performing liquid QC was provided. 4. When the IQCP was requested by the surveyor, no IQCP plan was made available at the time of survey. 5. In interview with the LD on 11/1/21 at 11:45 a.m. confirmed, the laboratory failed to define by written procedure: instruction for entering results in the patient record and control procedures for creatinine testing on the epoc blood analysis system.
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 the review of the manufacturer's instructions, QC records from 8/2/21 to the time of survey, patient test records and interview with the LD, the laboratory failed to perform QC at least once each day of patient testing for quantitative procedures, to include two control materials of different concentrations. Findings: 1. The epoc Blood Analysis System Manual requires at least 2 levels of fluid control for each lot in each shipment of cards. 2. The epoc Blood Analysis System cards for pH, pCO2, pO2, Sodium (Na), Potassium (K), Chloride (Cl), ionized Calcium (iCa), Lactate, Glucose, Hematocrit (Hct), Creatinine, Blood Urea Nitrogen (BUN), and total Carbon Dioxide (tCO2) are categorized as moderate complexity tests and require quality control at least once a day of patient testing with two control materials of different concentrations per 493.1256. 3 QC was not performed for 27 of 31 patient testing days for 27 of 31 patients. 4. No IQCP had been established to allow the laboratory to reduce the frequency of QC performance. 5. Interview with the LD on 11/1/21 at 11: 45 a.m. confirmed, the laboratory failed to perform QC at least once each day of patient testing for quantitative procedures, to include two control materials of different concentrations.