Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2221797	06/27/2023
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the review of the procedure "Siemens epoc IQCP", quality control (QC) documentation from 2/1/22 to 6/26/23, and interview with the laboratory director (LD), the laboratory failed to follow written procedures for the frequency of QC testing for creatinine. Findings: 1. Review of the Siemens epoc IQCP procedure, page 3, under Quality Control Plan revealed the following QC interval. External (Liquid) QC, Item 1." Gas ISE Metabolites Levels 1 & 3 run on new lot/shipments of test cards."; Item 2. "Test QC levels 1 & 3 Gas ISE Metabolites at least every 31 days." 2. Review of the QC control data from 2/1/22 to 6/26/23 revealed 5 occurrences where QC levels 1 & 3 were not performed at least every 31 days. a. QC Level 1 &3 performed on 4/27/22. Next QC Level 1 & 3 performed 5/31/22. Interval of 34 days. b. QC Level 1 & 3 performed on 6/30/22. Next QC Level 1 & 3 performed 8/18/22. Interval of 49 days. c. QC Level 1 & 3 performed on 8/29/22. Next QC Level 1 & 3 performed 10/3/22. Interval of 36 days. d. QC Level 3 only performed on 9/14/22. e. QC Level 1 & 3 performed on 10/27/22. Next QC Level 1 & 3 performed 12/14/22. Interval of 48 days. 3. Documentation of review by both TC #1 and TC #2 are present with "QC acceptable" in Last Review note column. 4. No documentation of unacceptable QC interval, corrective action or patient review was present. 5. Interview with the LD on 6/27/23 at 2:50 p.m. confirmed, the laboratory failed to follow written procedures for the frequency of QC testing for creatinine.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

	CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of QC documentation for creatinine testing on the Siemens epoc, lack of documentation of verification performance specification on new epoc test system, and interview with the LD, the laboratory failed to verify the performance specifications on the Siemens epoc host serial number (S/N) 20148521402465, reader S/N 39042 before use in patient testing. Findings: 1. Review of the QC documentation for creatinine revealed a review note entry for 10/6/22: "New Machine Validation /verification, QC acceptable" entered by TC #2. 2. Request was made for the verification study for new epoc analyzer. No documentation was made available at the time of survey. 3. QC documentation revealed the Siemens epoc host serial number (S/N) 20148521402465, reader S/N 39042 was placed into use on 10/3/22. 4. The LD provided a patient test volume of 98 patients from 10/3/22 to 6/27/23. 5. Interview with the LD on 6/27/23 at 3:20 p.m. confirmed, the laboratory failed to verify the performance specifications on the Siemens epoc host serial number (S/N) 20148521402465, reader S/N 39042 before use in patient testing.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of a patient test report and interview, the laboratory failed to include the performing laboratory's name and address on the patient test report. Findings: 1. Review of a selected patient test report revealed the performing laboratory's name and address were not on the report. 2. Interview with the LD on 6/27/23 at 3:05 p.m. confirmed, the laboratory failed to include the performing laboratory's name and address on the patient test report.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for

	acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based upon review of creatinine QC from 2/1/22 to 6/26/23, lack of documentation of corrective action, lack of documentation of patient remediation, and interview with the LD, the TC failed to ensure acceptable levels of analytic performance were maintained for creatinine testing on the Siemens epoc analyzer for released patient results. Findings: 1. Review of the creatinine QC from 2/1/22 to 6/26/23 revealed QC was not performed as required by the laboratory IQCP policy for creatinine testing. See D5401. 2. The QC log did not contain entries addressing the failure to perform QC at least every 31 days. 3. Request was made to review corrective actions for the QC interval failures. None were provided at the time of survey. 4. Request was made for orientation documentation of testing personnel to complete QC as required by the IQCP. None were provided at the time of survey. 5. Request was made for documentation of patient lookback or remediation for patient results released without acceptable QC within the required time interval. None were provided at the time of survey. 6. Interview with the LD on 6/27/23 at 2:50 p.m. confirmed, the TC failed to ensure acceptable levels of analytic performance were maintained for creatinine testing on the Siemens epoc analyzer for released patient results.