Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2183898	11/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Adventhealth Lab	7000 E Hampden Ave, Denver, CO	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review of the laboratory's quality control records and interview with the technical consultant (TC), the laboratory failed to retain manufacturer reference documents used in instrument quality control (QC) and calibration for the EPOC instrument used for blood gas and lactate testing, since the lab's initial certification survey on 02/18/2021. Findings include: 1. The laboratory failed to retain the manufacturer's quality control and calibration reference documentation for blood gas and lactate tests performed on the EPOC instrument, such as assay information sheets for control and calibration materials. 2. The lab performed approximately 550 blood gas and lactate tests on the EPOC instrument. 3. During an interview on 11/01/2023 at approximately 12:30 p.m., the TC confirmed that the manufacturer's reference range information inserts for each lot of control and calibration materials were scanned and filed in the instrument's QC binder, but was unable to locate them.
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 a record review and an interview with the technical consultant (TC), the laboratory failed to establish and follow a policy to assess the competency of two out of two TC's listed on the CMS-209 form since the last survey on February 18, 2021. Findings include: 1. A review of the laboratory's policies revealed that the laboratory failed to establish competency assessment policies for the TC position at this facility. 2. A review of the laboratory competency records, revealed the laboratory failed to document competency assessments for the position of TC since the last survey. 3. An interview on 11/1/2023, at approximately 10:40 AM, with the TC, confirmed that the competency assessments were not performed for the positions.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory technical consultant (TC), the laboratory director failed to delegate the responsibility of signing the attestation statements from the American Institute (API) proficiency testing (PT) program for tests performed in chemistry and hematology since January 2023. Findings include: 1. A review of the PT records from API for Events 1, 2, and 3 of 2023, revealed the laboratory TC consultant failed to have the delegated duty from the laboratory director for signing the attestation statements for the three events. 2. An interview on 11/1/2023, with the TC, at approximately 10:40 AM, confirmed the responsibility for signing the attestation statements for the PT was not delegated.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on document review of the laboratory's procedure manual and individual quality control plans (IQCPs); and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that a quality assessment policy was established for all phases of testing in chemistry and that documentation to support IQCP risk assessments was available since the initial certification survey on 02/18 /2021. The findings include: 1. A review of the IQCP for blood gas, lactate, D-Dimer,

	Troponin, and Human Chorionic Gonadotropin (HCG) revealed that the LD failed to evaluate potential failures or errors in the testing process and failed to provide documentation to support the IQCP's risk assesment and quality assurance (QA) processes used in the laboratory. 2. A review of the laboratory's procedure manual revealed that no quality assessment policy for all phases of testing was available to testing personnel and the TC. 3. In an interview on 11/01/2023, at approximately 2 p. m., the TC confirmed that the LD failed to ensure that a quality assessment policy was established and available and that the risk assessments for the IQCP failed to evaluate potential failures or errors in the testing process.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical consultant (TC), the laboratory director failed to have policies and procedure manuals approved and available to all personnel performing tests in chemistry and hematology for the laboratory location since August 2023. Findings include: 1. A record review of the laboratory policies and procedures, revealed the laboratory director failed to have an approved procedure manual for tests performed in chemistry and hematology available to personnel and specific for the laboratory location since August 2023. 2. An interview on 11/1/2023, at 12:15 PM, with the TC, confirmed that the procedure manual for the laboratory did not include specific procedures for the location or approval dates from the laboratory director.