Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2117329	08/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Adventhealth Ed & Urgent Care Meridian Lab	9949 S Oswego, Ste 100, Parker, 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
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 review of proficiency testing documentation and staff interview, the laboratory director or designee failed to sign the attestation statement for proficiency testing modules in 2018. Findings include: a) Review of College of American Pathologists (CAP) proficiency testing records revealed the laboratory director or designee did not sign the attestation statement for the following modules in 2018: a. 1st event, 2018FH9 (FH9) Hematology, (1 of 2 events) b) In an interview conducted on August 20, 2018 at 10:00 AM, the technical consultant confirmed the attestation statements were not signed for the modules mentioned above by the laboratory director or designee.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the Point of Care (POC) Quality Program and staff interview, the technical; consultant failed to follow the laboratory's Quality Assurance (QA) plan for

	documentation of training and review of temperature logs for 2 of 2 years (2016-2018). Findings include: 1) Review of the POC Quality Program revealed the technical consultant did not follow the laboratories policy for documentation of initial training for each employee. The POC Quality Program states on page 4 & 5 under the Education, Training and Competency section: b. "For non-waived testing all TPs must receive initial training, semi-annual competency assessment in the first year" d. "Documentation of the initial training/ competency assessment, semiannual competency and annual competency shall be maintained in the employee's education file on the testing unit or in some cases on training logs." a) In an interview conducted on August 20, 2018 at 10:30 AM, the technical consultant confirmed there was no initial training documentation for years 2016-2018. 2) Review of the POC Quality Program revealed the technical consultant did not follow the laboratories policy for monitoring the temperatures in the laboratory for the following: a) The POC Quality Program states on page 9 under the Temperature monitoring section "Temperature logs will be reviewed monthly by the POC Specialist or designee." The Technical Consultant failed to monitor for the following dates: i. August 2016 - December 2016 ii. January 2017 to December 2107 iii. January 2018 to August 2018 b) In an interview conducted on August 20, 2018 at 10:30 AM, the technical consultant confirmed there was no review of temperature log sheets from August 28, 2016 to August 17, 2018 3) Review of the POC Quality Program revealed the technical consultant did not follow the laboratories policy for documenting corrective action for out of range temperatures in the laboratory for the following month in 2016: a) No corrective action was documented for temperatures out of range for 25 out of 30 days in September 2016, b) In an interview conducted on August 20, 2018 at 10:30 AM, the technical consultant confirmed there was no corrective action for temps out of range for the above date.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing documentation and staff interview, the laboratory director or designee failed to review the proficiency testing evaluation for proficiency testing modules in 2017. Findings include: a) Review of College of American Pathology (CAP) proficiency testing records revealed the laboratory director or designee did not reviewed the evaluation records for the following modules in 2017: a. 3 rd event, PCARM-C 2017, Plasma Cardiac Markers (1 of 3 events) b. 3 rd event, AQI-C 2017, Critical care Aqueous Blood Gas (1 of 3 events) b) In an interview conducted on August 20, 2018 at 10:00 AM, the technical consultant confirmed the proficiency testing evaluation records were not reviewed for the modules mentioned above by the laboratory director or designee.
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 review of the Technical Consultant, POC - Authorization/ Responsibilities Procedure and staff interview, the Laboratory Director failed to delegate in writing to the Technical Consultant duties that required director review. Findings include: 1) Review of the current Technical Consultant, POC - Authorization/ Responsibilities Procedure effective 02/18/2016 revealed the laboratory director delegated the responsibilities below to specific names of three Technical Consultants that no longer work in the laboratory at Centura ER & Urgent Care- Meridian. a. Review of policies and procedures developed by Larkin for accuracy and regulatory compliance. b. Approval (sign off) on all monthly and periodic documents requiring review. This includes, but is not limited to, maintenance sheets (instrument or basic lab functions), quality control logs or charts, reagents and calibration logs, CAP attestation statements, etc. In addition, the Laboratory Director may also delegate this to additional staff (see specific authorization form- if any). In an interview conducted on August 20, 2018 at 11:30 AM, the technical consultant confirmed that no currently employed Technical Consultants are listed in the Technical Consultant, POC - Authorization/ Responsibilities Procedure since her start date of 08/28/2017.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of staff competency records and staff confirmation, the technical consultant failed to perform semi-annual competencies on 2 of 13 new employees for 2016 and 2017. The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of staff competency records and staff confirmation, the Technical Consultant failed to perform semi-annual competencies on 2 of 13 new employees in the first year of employment for 2016 and 2017. Findings include: A) Review of competency records revealed TP 14 started employment at Centura ER & Urgent Care - Meridian on 08/22/2016 and no semi-annual competency assessment performed in

	the first year of employment with the Centura ER & Urgent Care- Meridian B) Review of competency records revealed TP 20 started employment at Centura ER & Urgent Care - Meridian on 01/13/2017 and no semi-annual competency assessment performed in the first year of employment with the Centura ER & Urgent Care-Meridian B) Interview conducted on 08/17/2018 at 10:15 AM the Technical Consultant confirmed that TP 14 and 20 only had one competency assessment performed in their first year of employment with Centura ER & Urgent Care-Meridian.