Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D1028781	02/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Adlera Laboratory, Llc	601 1st Avenue North, Great Falls, MT	

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
D0000	Based on an unannounced complaint survey conducted on February 28, 2023, deficiencies were cited for Adlera Laboratory, LLC, in Great Falls, MT.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on a record review of patient results reports, order forms from the authorized person, and interview with student intern #1, the laboratory failed to ensure the information from the requisition or order forms were entered accurately into the laboratory information system (LIS) for four out of four patients from February 21, 2023 to February 27, 2023. Findings: 1. A review of the revised patient result's report (213702) revealed the laboratory failed to perform the Hemoglobin A1c test in a timely matter due to the order being omitted from being entered into the LIS on February 20, 2023. 2. Review of three out of three patient results reports (213697, 213738 and 213702), and corresponding order forms revealed the collection dates were entered incorrectly into the LIS from February 20, 2023, and February 21, 2023. 3. Interview with the student intern #1 on February 27, 2023, at 2:13PM confirmed the laboratory failed to accession information correctly into the LIS system from February 20, 2023, to February 22, 2023.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)

	Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, record review of patient results reports, procedures, and interview with student intern #1, the laboratory failed to establish and follow written procedures to maintain specimen integrity for three out three patient specimens and maintain positive identification for one of one patient's specimen throughout the testing process when performing testing on the Siemens Atellica chemistry and immunoassay analyzer from February 17, 2023 to February 24, 2023. Findings: 1. Observed February 28, 2023, at 11:30 AM several racks of chemistry and hematology blood specimen tubes in laboratory refrigerator of samples tested from February 21, 2023, through February 24, 2023. 2. Review specimen tube labels revealed the laboratory staff failed to follow its' Specimen Collection, Processing and Rejection procedure to have two identifiers on one of the specimen tube labels found in the racks. 3. A review of patient result reports (213619, 213644, and 213629) with specimen collection dates of February 17, 2023, and tests performed dates of February 21, 2023, for analytes calcium (Ca), glucose, total protein, Thyroid-Stimulating Hormone (TSH), and Vitamin B-12 revealed the laboratory did not adhere to the manufacturer's guidelines to ensure samples were not tested past their sample stability criteria. 4. Review of Quality Assurance (QA) Plan revealed the laboratory failed to follow their procedure for unacceptable samples as stated, "3. Specimen handling, collection, and labeling ...that the specimens are collected, handled, stored, and preserved as appropriate, that each written testing procedure will identify unacceptable samples ..." 5. An interview with student intern #1 on February 27, 2023, at 12:15 PM confirmed the laboratory failed to label one specimen tube with two identifiers and follow the manufacturer's instructions for specimen stability from February 17, 2023, to February 21, 2023.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on a record review of patient results reports, order forms from the authorized person, procedures, and interview with student intern #1, the laboratory failed to monitor, assess, and correct problems identified in their pre-analytical process from February 17, 2023, to February 27, 2023. Findings: 1. A review order form for (Accession 213702) revealed the laboratory staff failed to follow their Quality Assurance (QA) Plan to document corrective action for the omission of Hemoglobin A1c order on February 21, 2023, as stated, "2. Test Tracking-Requisitions ...Should omissions be found in the Dr. List, corrective actions will be implemented ..." Cross refer D5309 2. Review of Quality Assurance (QA) Plan revealed the laboratory failed to prevent stability issues and identify unacceptable samples per their procedures, "3. Specimen handling, collection, and labeling ...that the specimens are collected, handled, stored, and preserved as appropriate, that each written testing procedure will

	identify unacceptable samples ..." Cross refer D5311. 3. The Quality Assurance (QA) Plan lacked instruction for provider communications or corrective action reports for the delay of testing from February 17, 2023, to February 22, 2023. 4. Interview with the student intern #1 on February 27, 2023, at 2:13PM confirmed the laboratory failed to monitor, assess and correct problems identified with their specimen labeling, LIS accessioning, specimen stability and provider communication from February 17, 2023, to February 22, 2023