Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D1028781	01/28/2021
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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of chemistry, hematology, molecular and urinalysis procedures, the laboratory failed to include normal values for chemistry, microscopic urinalysis and failed to have a step-by-step procedure for microscopic urinalysis (refer to D5403); failed to follow defined criteria to document temperature for molecular testing (refer to D5413); failed to document corrective action when molecular room temperatures deviated from acceptable range (refer to D5781); and failed to establish or verify the criteria for chemistry acceptability of all control materials (refer to D5439).
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 on review of the chemistry, urinalysis, coagulation, and hematology procedures, and interview with technical supervisor (TS) #1, the laboratory failed to include in their procedure manuals reference intervals (normal values) for chemistry, and microscopic urinalysis; failed to include a procedure to address instrument flags for the Sysmex XN-430 hematology analyzer; and failed to have a step by step procedure for review for microscopic urinalysis. Findings: 1. No reference intervals (normal values) were available in the chemistry procedure manual. 2. No reference intervals (normal values) were available in the urinalysis procedure manual for microscopic urinalysis. 3. No procedures for addressing Sysmex XN-430 analyzer flags in the hematology procedure manual. 4. No procedure for microscopic urinalysis was available for review. 5. Interview with the TS #1 on January 28, 2021 at 11:00 AM confirmed the laboratory failed to include normal values for chemistry, microscopic urinalysis; failed to have procedure to address instrument flags for the hematology analyzer; and failed to have a step-by-step procedure of microscopic urinalysis.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of molecular procedure and interview with technical supervisor (TS) #1, the laboratory failed to record temperature for the molecular dry heat block (Eppendorf ThermoMixer C). Findings: 1. Review of laboratory procedure for Lyra Sars-COV2 revealed "Heat the plate or tubes at 95C 1C for 10 minutes." 2. No temperature log for the dry heat block was available for review. 4. Interview with TS #1 on January 28, 2021 at 9:45 AM, confirmed the laboratory failed to document temperatures for the dry heat block.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes of sodium, potassium, and chloride, patient reports and interview with the technical supervisor (TS) #1, the laboratory failed to perform at least a three point (a minimal, mid-point, and maximum) calibration verification every six months. Findings: 1. Review of 2019 and 2020 calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes: sodium, potassium, and chloride, revealed the laboratory failed to perform a calibration including, at least, a minimal, midpoint, and maximum value for each analyte, every six months. 2. Review of patient reports showed 14,652 K/NA/CL results were reported for 2020. 3. Interview with the TS #1 on January 28, 2021 at 9:55 AM confirmed the laboratory failed to perform at least a three-point calibration for sodium, potassium, and chloride on the Siemens Dimension EXL 200 chemistry analyzer every six months.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of molecular procedure and interview with technical supervisor (TS) #1, the laboratory failed to document corrective action for the molecular room temperature being outside the acceptable range of 20C to 25C for five out of six days in January. Findings: 1. Review of laboratory procedure for Lyra Sars-COV2 revealed

	"Assay Procedure. Run the following procedures at controlled room temperature of 20C to 25C." 2. Review of Molecular Room Temperature Log for January 22 -28, 2021, revealed the temperature values recorded were above 25C for five out of six days. 3. Interview with TS #1 on January 28, 2021 at 9:45 AM, confirmed the laboratory failed to document corrective actions when temperatures deviated from acceptable range.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform competency assessment twice during the first year for the technical Supervisor (TS) #1. Findings: 1. Review of Adlera Labs Employees Files revealed that the laboratory failed to perform semiannual competency assessment for the TS#1 during the first year of patient testing in 2019. 2. Confirmed during interview with TS #1 on 1/28/2021 at 1130 AM, the laboratory failed to perform competency assessment semiannual during the first year of patient testing.