Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D1028781	08/03/2022
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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of maintenance documentation, procedure manual, observation of pipettes, automated pipette system, and microscope, and interview with Technical Supervisor (TS) #1, the laboratory failed to establish and follow procedures for performing function checks to verify the accuracy of six pipettes, one automated pipette system, and one microscope. Findings include: 1. No documentation of certification of performance was available to show the laboratory verified the performance of six of six pipettes and one automated pipette system from 3/31/2021 to 8/3/2022 and one microscope since 2016. 2. Observation of Evolve pipettes: 1-20 microliter, 1-20 microliter, 20-200 microliter, 100-1000 microliter, and two VIAFLO electronic pipettes: The 8-channel 125 microliter, 12-channel 1250 microliter, and one VIAFLO automated pipette system located in the laboratory lacked labels for function check. 3. Observation of one microscope located in the laboratory revealed a certification label expired in 8-18-2016. 4. Review of Quality Assessment and Control Policies and Statement revealed, "Preventative Maintenance & Service-Schedules, charts, and other documents pertaining to the maintenance of laboratory equipment

	are to be kept for any instrument in the lab." The policy failed to define function checks for the microscope and pipettes. 5. Interview with TS #1 on August 3, 2022, at 2:30 PM, confirmed these findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of procedure manual, laboratory records and interview with the Technical Supervisor (TS)#1, the laboratory failed to document the intended staining characteristics for each day manual differentials slides were stained. Findings include: 1. Review of hematology records revealed the laboratory failed to document the staining quality of manual differential slides each day of Wright Stain use from January 1, 2020, to August 3, 2022. 2. Review of Peripheral Smear Preparation and Criteria for Smear Review procedure lacked how the laboratory would document staining quality control checks on manual differentials slides. 3. Interview on August 3, 2022, at 12:30 PM with TS #1, confirmed the laboratory failed to document staining quality of manual differential slides from January 1, 2020, to August 3, 2022.