Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1048321	12/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Aspr Mission Support Center	6701 English Muffin Way, Frederick, MD	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to follow its own procedure for the documentation of failed quality control limits for hematology. Findings: 1) A review of the Laboratory Policy and Procedure under General in the Laboratory Control Policy stated- 3.2 "3.2 All quality control data that exceeds the manufacturers established tolerance limits will be documented on the ASPR Laboratory Quality Control Problem Log along with the action performed to correct the quality control discrepancy." 2) In an interview with the laboratory director on 12/7 /2022 at 3pm the surveyor requested a sample of the Laboratory Quality Control Problem Log. The laboratory director confirmed that the laboratory did not have a QC problem log.
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 record review and interview the laboratory failed to provide written procedure for the resolution of flagged specimens in hematology. Findings: 1) A review of the Laboratory Policy in Hematology under Running Whole Blood samples it stated: 5.7.4 If flags appear for a sample, you refer to "What Flags and Codes Mean Table" 2) In interview with the laboratory director on 12/7/2022 at 3pm the surveyor requested to see the "What Flags and Codes Mean Table". The surveyor was referred to the manufacturer's instruction manual. Flag codes for white blood cell discrepancies and platelet clumps directed the technician to perform a manual differential. The laboratory director stated that manual differentials were not performed by the lab and confirmed that a laboratory procedure for resolution of flags was not established.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to provide documented maintenance as outlined in its procedure. Findings: 1) A review of the ASPR Laboratory Policy and Procedure under Routine Maintenance Policy showed maintenance requirements for Coulter Hematology Analyzer as outlined below for periods when the analyzer is in use: 4.5.1 Perform Startup and Shutdown daily 4.5.2 Clean the outside of the instrument with a damp cloth and distilled water weekly to prevent the buildup of corrosive deposits. 4.5.3 Clean up spills promptly - pay particular attention to the probe wipe housing 4.5.4 Clean the inside of the instrument (behind the front door and beneath the bath shield) with a damp cloth and distilled water if evidence of corrosive deposits exists. Be careful not to wipe contaminants into the bath. 4.5.5 Clean the filter in water and dry weekly 2) In an interview with the laboratory director on 12/7/2022 at 3pm a request for a sample of a maintenance documentation log was requested by the surveyor. The laboratory director confirmed that there is no documentation of maintenance for periods the analyzer is put into use.