Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0978422	06/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Support Laboratory	Bldg 469 Rms 120, 120a, 121 & 200, 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
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 quality control (QC) worksheets, Positive Control Lot Comparison Reports, the procedure manual and interview with the technical supervisor, it was determined the laboratory failed to include in it's Standard Operating Procedure (SOP) for the Anti-IL15 ELISA assay, a defined naming format (scheme) when new lot numbers of low and high positive controls are being studied. Findings include: 1. In Version #7 of the "ELISA Method for the Detection of Human Antibodies to Recombinant Human Interleukin 15 (IL-15) in Human Serum" SOP, signed as effective on 8/9/16 in Sections 9.8.4 (Low Positive) and 9.9.3 (High

	Positive), states "Label vials with name, concentration, lot number, aliquot volume and expiration date." 2. In conversation with the technical supervisor, the lab prepares two levels of positive controls on both the ELISA assays every six months. 3. The surveyor reviewed new lot acceptable criteria worksheet report for anti-IL15 positive controls dated May 29, 2018 that lists the Low Pos QC Lot numbers for the Old and New Lots as "L120717" and "L052518" respectively; the High Pos QC Lot numbers for the Old and New Lots as"H120717" and "H052518" respectively. 4. During interview with the technical supervisor at approximately 2:00pm, when asked how the personnel preparing the new lots of QC will be identified, there was an admission the lab did not define the naming format in the SOP when new lot numbers are prepared in-house. ELISA-Enzyme Linked Immunosorbent Assay
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) worksheets, Positive Control Lot Comparison Reports and interview with the technical supervisors, it was determined the laboratory technical supervisors, who prepared and reviewed Positive Control Lot Comparison Report for one of one new QC Pos lot of Anti-IL15 prepared since January 2018, failed to ensure the listed accepted (expected) values were accurately listed. Findings include: 1. The surveyor reviewed new lot acceptable criteria worksheet report for anti-IL15 positive controls dated May 29, 2018 that lists the Low Pos QC acceptable range for the Old and New Lots as "757 - 1,056 (ng/mL)"; the High Pos QC acceptable range for the Old and New Lots as"1,738 - 4,260 (ng/mL)". 2. The surveyor compared those Positive QC lot ranges to those as stated on the Anti-IL15 QC Sheet on 5/29/18 and found the Positive QC ranges were different then those on the new lot acceptable criteria worksheet report, listed as "910 - 1,539 (ng/mL)" for the Low Positive control and "3,276 - 6,255 (ng/mL)" for the High Positive control. 3. The New Lot Comparison Report for the study performed on May 29, 2018, identified TS2 as the preparer and TS1 as the reivewer/acceptor. 4. During interview with technical supervisors (TS1 and TS2) at approximately 2:15pm, there was an admission from both lab technical supervisors, that they failed to ensure the accuracy of the transcribed values from the New Lot Comparison Report and the QC Worksheet.