Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0978422	07/21/2026
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
D0000	A recertification survey was conducted on July 21, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on direct observation, review of quality control (QC) records, laboratory test records, written policies and procedures, and confirmed in interview with the Technical Supervisor (TS), the laboratory failed to take corrective action by evaluating patient test results obtained since the last acceptable test run after QC failures on the Meso Scale Discovery (MSD) Quick Plex SQ 120 instrument for 4 of 79 QC runs on testing days between 7/8/2025 and 4/15/2026 (Random Review). Findings Included: 1) In direct observation at 4:17 PM, one MSD Quick Plex instrument (Serial Number SQ120) was observed in the laboratory. 2) Review of the laboratory's QC records (QC lots: QC1063025, QC2063025, QC3063025) revealed the following dates with QC failures for Interferon-gamma (IFN-y), and patient evaluations which did not extend to the last acceptable test run: a. 2/27/2026, Assay 13947 - QC2 Value: 84.6, Highest Acceptable Value: 77.8; QC3 Value: 34.9, Highest Acceptable Value 30.9. Previous acceptable assay run on 2/26/2025 (Assay 13946), 1 patient run b. 3/02/2026, Assay 13948 - QC2 Value: 80.4, Highest Acceptable Value: 77.8; QC3 Value: 32.5, Highest Acceptable Value 30.9. Second QC run failure QC2

	Value: 83.5, Highest Acceptable Value: 77.8; QC3 Value: 33.7, Highest Acceptable Value 30.9. Previous acceptable assay run on 2/26/2025 (Assay 13946), 1 patient run c. 3/16/2026, Assay 13953 - QC2 Value: 79.6, Highest Acceptable Value: 77.8; QC3 Value: 31.6, Highest Acceptable Value 30.9. Previous acceptable assay run on 3/10 /2026 (Assay 13950), 1 patient run d. 4/15/2026, Assay 13975 - QC2 Value: 79.9, Highest Acceptable Value: 77.8; QC3 Value: 32.7, Highest Acceptable Value 30.9. Previous acceptable assay run on 4/10/2026 (Assay 13971), 2 patients run 3) Review of the laboratory QC policy and procedure titled 'Clinical Support Laboratory Quality Control Testing - ELISA Based Assay, Document ID: 142001' stated the following on page 3 of 9: "QC results for each test are compared against an established control range. A QC result outside of the control range, will be investigated, when warranted, and appropriate action taken to resolve the issue." 4) In an interview on 7/21/2026 at 2: 53 PM, the TS confirmed, during QC failure events, the laboratory did not perform patient evaluations to the last acceptable test run.