Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0663183	07/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Aids Monitoring Lab	Bldg 469 Rooms 12,256-258, 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.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's written policies and procedures, and interview with the Technical Supervisors (TS) #1 and #2 according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to establish and follow written policies and procedures for specimen transportation condition (temperature) for 2 of 2 years (2025 and 2026). Findings Included: 1) Review of the laboratory's written policy titled 'AIDS Monitoring Laboratory Procedure for Specimen Collection and Data Handling' stated the following on page 5 of 9: "5.2 Specimen Rejection: Specimens must be rejected and a new specimen obtained in the following instances ...5.2.3 Specimens received improperly shipped (excessive heat or cold)". The policy failed to include specimen transportation requirements (i.e. temperature), for patients (self-collection), outside clinics, and couriers. 2) In an interview with staff at 11:30 AM, TSs #1 and #2 confirmed the laboratory failed to have written policies and procedures for specimen transportation requirements, such as temperatures, and could not define exact temperature parameters which would be considered excessive heat or cold.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, review of manufacturer's instructions, the laboratory's refrigerator temperature settings, and interview with Technical Supervisors (TS) #1 and #2 according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to define refrigerator temperature ranges in accordance with manufacturer instructions for 30 of 30 Quality Control (QC) reagents and beads of various manufacturers. Findings Included: 1) During a laboratory tour at 11:01 AM, the following refrigerators and nodes were observed, with reagents stored within: a. Refrigerator Node 11, Probe 2, 27, S099947: i. 2 Status Flow Cytometry Controls, Lot # FC076, Manufacturer storage temperature requirements 2 to 8 degrees Celsius. ii. 2 Status Flow Cytometry Controls, Lot #FC0726-4L, Manufacturer storage temperature requirements 2 to 8 degrees Celsius. iii. 12 Sysmex XN-L Check Controls, Lot #6121, Manufacturer storage temperature requirements 2 to 8 degrees Celsius. b. Refrigerator 2 (Flow Cytometry), Thermo Scientific TSG NIH#C141478: Node 11, Alarm PT: 0004: i. Becton Dickinson (BD) Cytometer Setup and Tracking (CST) beads Ref # 662414, Lot # 514003 - 3 vials, and Lot # 515375 - 6 vials, Manufacturer storage temperature requirements 2 to 8 degrees Celsius. ii. Becton Dickinson (BD) Flow Cytometry (FC) beads Ref # 662961, Lot# 5181469 - 2 boxes, Lot #5363702 - 1 box, Lot #6030036 -2 boxes, Manufacturer storage temperature requirements 2 to 8 degrees Celsius. 2) Review of the refrigerators alarm ranges revealed a range of 1 to 7 degrees Celsius. 3) In an interview at 11:05 AM, TS #1 and 2 confirmed the refrigerators' lower threshold of the acceptable temperature alarm range was outside of manufacturer requirements.