Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0957207	04/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Of Parasitic Disease	Bldg 4/ 211, Bethesda, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures, CMS Laboratory Personnel Report (Form CMS-209), competency assessment records, and an interview with the Laboratory Director, the laboratory failed to establish and implement written policies and procedures for assessing competency based on position responsibilities for one of one individual fulfilling the roles of Clinical Consultant, Technical Supervisor, and General Supervisor. Findings: 1. On April 9, 2025, at approximately 12:30 p.m., a review of the laboratory 's policy titled QC-QA Plan revealed the absence of any documented process for assessing competency specific to the responsibilities of personnel serving as Clinical Consultant, Technical Supervisor, and General Supervisor. 2. On April 9, 2025, at approximately 10:30 a.m., a review of the CMS Laboratory Personnel Report (Form CMS-209) indicated that one individual was listed as fulfilling the roles of Clinical Consultant, Technical Supervisor, and General Supervisor. 3. On April 9, 2025, at approximately 12:00 p.m., a review of the laboratory 's competency assessment records revealed that no competency documentation was available for the individual identified as serving in the aforementioned roles. 4. On April 9, 2025, at approximately 12:40 p.m., an interview with the Laboratory Director confirmed that the laboratory does not have policies or procedures in place for assessing competency of individuals in roles other than testing personnel.
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 a review of the laboratory 's policies and procedures, direct observation and staff interview conducted during a laboratory tour, the laboratory failed to monitor and document ambient room temperature and humidity, as well as internal temperatures for two freezers and two refrigerators used to store laboratory reagents and patient specimens. Findings: 1. On April 9, 2025, at approximately 1:00 p.m., a review of the laboratory 's policy titled QC-QA Plan revealed a section labeled Equipment Monitoring, which stated: "All instruments such as freezers, refrigerators, and incubators are monitored manually or electronically by alarm system and recorded on each day of use. Refrigerator temperature should be between 2 and 8 C. Freezer temperature should be between -25 and -15 C. Ambient room temperature between 50 and 90 F is appropriate for testing procedures." 2. On April 9, 2025, at approximately 11:00 a.m., a physical inspection of Room 11S216, where laboratory testing was performed, revealed that ambient room temperature and humidity were not being monitored or documented. No temperature or humidity logs were available for review at the time of inspection. 3. On April 9, 2025, at approximately 11:00 a.m., observation of laboratory cold storage units revealed the presence of: -Two freezers labeled #8 (NIH ID# 02229735) and #13 (NIH ID# 02309916) -Two refrigerators, one labeled with NIH ID# 02269071 and another labeled probe #14 (no visible NIH ID#) All four units contained laboratory reagents and patient specimens. No internal temperature probes were observed inside any of the units. Furthermore, no temperature monitoring logs (manual or electronic) were available for review at the time of inspection. 4. On April 9, 2025, at approximately 11:15 a.m., an interview with the Laboratory Director confirmed that the laboratory had not been monitoring or documenting room temperature, humidity, or the temperatures of the two freezers and two refrigerators since relocating to its current location on February 14, 2025.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(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. (b)(2)(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 the laboratory 's policies and procedures, equipment maintenance records, and an interview with the Laboratory Director, the laboratory failed to perform and document annual pipette calibrations for 96 out of 96 pippetes as

	required by its own policy since March 20, 2023. Findings: 1. On April 9, 2025, at approximately 1:00 p.m., a review of the laboratory ' s policy titled QC-QA Plan revealed a section labeled Equipment Monitoring, which states: "Pipettes are calibrated every 12 months." 2. On April 9, 2025, at approximately 1:00 p.m., a review of the laboratory ' s equipment maintenance records showed that 78 single-channel pipettes, 15 multichannel pipettes, and 3 multichannel electronic pipettes were last calibrated on March 20, 2023. No documentation of subsequent pipette calibrations was available for review at the time of inspection. 3. On April 9, 2025, at approximately 1:15 p.m., an interview with the Laboratory Director confirmed that pipette calibrations had not been performed annually, as required by the laboratory ' s own policy.