

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0957207	(X3) Date Survey Completed 04/06/2023
Name of Provider or Supplier Laboratory Of Parasitic Disease	Street Address, City, State 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
D0000	The laboratory of Parasitic Disease was surveyed under 42 CFR part 493 CLIA regulations. The following standard deficiencies were found during the announced routine CLIA recertification survey performed on April 6, 2023:
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency documentation review and an interview with testing personnel #1 (TP1) and technical supervisor #2 (TS2), the laboratory failed to verify the accuracy of tests performed that is not included in subpart I of this part at least twice annually. Findings include: 1. On 04/6/2023 at 11:45 AM, a review of the Quality Assurance Plan Version 6 (7/28/2021), section Proficiency/Accuracy Testing required the following procedures: Once a year, 8 blinded - but previously tested - specimens are repeated to ensure that similar results are obtained. 2. On 04/6/2023 at 12:25 PM, a review of the proficiency testing sheets, showed that proficiency testing / Accuracy testing had been performed once a year for these analytes. a. Antifilarial IgG and Antifilarial IgG4: 3/15/21, and 2/28/22 b. Tso11R13 qPCR: 8/7/20, 7/30/21, 1/12/22, and 3/31/23 3. On 04/6/2023 at 1:10 PM, the laboratory TP1 and TS2 confirmed the above findings.</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test</p>

system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on observation, a lack of documentation, and an interview with testing personnel #1 (TP1), the laboratory failed to demonstrate that they had established test performance specifications for their Antifilarial IgG and Antifilarial IgG4 laboratory-developed tests (LDT) before patient testing in new Bio Plex 200 System Reader to detect the identity and determine the quantity of the analytes. Findings include: 1. A tour of the laboratory on April 6, 2023, at 10:00 AM, revealed it was one Bio Plex 200 System Reader (Serial# LX10021091421) in the laboratory for performing Antifilarial IgG and Antifilarial IgG4 tests. 2. The laboratory did not establish test performance specifications for Antifilarial IgG and Antifilarial IgG4 tests, and there was no documentation available at the time of the survey. 3. Interview with the TP1 on 04/6/2023 at 11:30 AM confirmed the above finding and the fact the laboratory started the patient testing for Antifilarial IgG and Antifilarial IgG4 tests on 7/9/2021.