

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2196263	(X3) Date Survey Completed 06/18/2025
Name of Provider or Supplier New Discovery Laboratories	Street Address, City, State 701 E Pratt Street, 5005, Baltimore, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not ensure that the attestation statements for the 2024 proficiency test events were signed and dated by the testing staff. Findings: 1. The laboratory director and testing person(s) are reported to the proficiency test provider (API) electronically when the results are submitted to the provider for evaluation and the laboratory prints a copy of the attestation for staff to sign and date. 2. The laboratory policy is to use the printed attestation report as a signed attestation, but there was no written procedure to ensure that the printed report with the preprinted staff names meets the definition of an electronically signed signature (where the person whose name that is printed on the report is using their secure pass code(s) to enter their name onto the report). The director and testing staff did not sign and date the printed attestation report. 3. This was confirmed during interview with laboratory staff on May 15, 2025 at 11:30 am.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and interview, the laboratory did not document their evaluation of proficiency test results that were not graded by the proficiency test provider due to the providers decision to not evaluate for reasons such as a limited number of participants. Findings: 1. Review of the three proficiency test events evaluated in 2024 by the proficiency test provider (API) for molecular biology testing showed that one of twenty analytes reviewed were not evaluated by the proficiency test provider. 2. The laboratory did not have documentation to show that it evaluated the analyte that the provider did not grade to see if their responses were in line with the majority of respondents or explain why the data provided by the provider could not be used to provide a reliable evaluation of the test results submitted by the laboratory. 3. This was confirmed during interview with laboratory staff on May 15, 2025 at 11:30 am.