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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>31D0989131         | <b>(X3) Date Survey Completed</b><br>03/12/2024 |
| <b>Name of Provider or Supplier</b><br>Meghan M Caruso Do  | <b>Street Address, City, State</b><br>875 Route 73 North, Suite D, Marlton, NJ |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D3009</b>              | <p><b>FACILITIES</b><br/>CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain a NJCLL for 2024 or any prior years. The Program Manager for the Clinical Laboratory Improvement Services (CLIS) confirmed on 3/8/24, prior to the recertification survey, that the laboratory did not have a NJCLL license for 2024 or any prior years. The Laboratory Director confirmed on 3/12/24 at 12:00 pm that the laboratory did not maintain a NJCLL for 2024 or any prior years.</p> |
| <b>D5401</b>              | <p><b>PROCEDURE MANUAL</b><br/>CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have a procedure for the DTM testing from 11/10/22 to the date of survey. The TP confirmed on 3/12/24 at 11:00 am that the laboratory failed to have the aforementioned procedure.</p>   |

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (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 surveyor review of the Taylor thermometers used for incubation and in the refrigerator and interview with the Testing Personnel (TP), the laboratory failed to provide documentation of calibration for the Taylor thermometers used in the laboratory from 11/10/22 to the date of the survey. The findings include: 1. The laboratory could not provide documentation of calibration for the Taylor thermometers used for incubation and in the refrigerator. 2. The TP confirmed on 3/12/24 at 11:15 am that they could not provide documentation of calibration of the Taylor thermometers.