| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 33D0892094 | 02/26/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ronald A Primas | 952 Fifth Ave Suite 1d, New York, NY | |

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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Standard Operating Procedures (SOPs), lack of thermometer calibration records, as well as interview with the Technical Consultant (TC), the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no calibration certificate documentation for the thermometers utilized for laboratory area room and refrigerator temperature monitoring where reagent storage occurred. It was noted that the respective refrigerator thermometer probe included a calibration tag indicating recalibration due |

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| | in 2023. 2. The current, approved SOPs did not include instructions for thermometer calibration and calibration certificate retention. 3. The TC confirmed the findings on February 26, 2025, at approximately 10:45 A.M. |