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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 33D2109963 | (X3) Date Survey Completed 08/22/2023 |
| Name of Provider or Supplier Integrated Medical Professionals, PLLC | Street Address, City, State 340 Broadhollow Road, Suite E, Farmingdale, 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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| D5401 | <p>PROCEDURE MANUAL 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: Based on review of the corrected report standard operating procedure, the laboratory failed to define result verification objective criteria when a corrected report was generated. Confirmed findings by interview with the laboratory director on August 22, 2023, at approximately 1:30 P.M.</p> |
| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.</p> |

(12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the molecular laboratory refrigerator temperature log, the laboratory failed to comply with acceptable temperature range of 2 - 8 C. Findings: 1. Molecular laboratory refrigerator was out of acceptable temperature range from August 7, 2023, through August 12, 2023. 2. Approximately thirty to thirty-five untested patient specimens were stored in the molecular laboratory refrigerator at the time of the temperature deviation. 3. Confirmed findings by interview with laboratory director on August 22, 2023, at approximately 2:00 P.M.