

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0706604	(X3) Date Survey Completed 08/19/2025
Name of Provider or Supplier Great Lakes Physician Pc	Street Address, City, State 500 Sterling Drive, Orchard Park, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of waived testing manufacturers' package insert instructions, lack of Quality Control (QC) documentation, as well as interview with the Testing Personnel (TP), the laboratory failed to follow manufacturer's instructions for performing the test. FINDINGS: 1. There was no documentation of Quality Control (QC) performance for the Medline hCG Pregnancy Test strips or the Siemens Clinitest hCG Pregnancy Test cassettes used for patient testing. 2. This is contrary to instructions indicated in the respective manufacturers' package inserts. 3. The TP confirmed the findings on August 19, 2025, at approximately 1:15 P.M.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records as well as interviews with the Laboratory Team Leader (LTL) and TP, the laboratory failed to document review and evaluation of the results obtained on PT performed. FINDINGS: 1. There was no documentation of Laboratory Director (LD) review and signature on the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT summary</p>

document for the 2025 first event. 2. The LTL and TP confirmed the findings on August 19, 2025, at approximately 2:30 P.M.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of twice-a-year verification data, Standard Operating Procedures (SOPs) and Quality Assurance (QA) policies, as well as interviews with the LTL and TP, the laboratory failed to comply with SOPs for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements. FINDINGS: 1. Primary post vasectomy semen analysis results were recorded on the twice-a-year verification log sheets for 2023, 2024, and 2025. However, no secondary or confirmatory results were documented to verify the accuracy of post vasectomy semen analysis. 2. This is contrary to instructions indicated in the current approved SOPs as well as QA policies. 3. The LTL and TP confirmed the findings on August 19, 2025, at approximately 2:45 P.M.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(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.

This STANDARD is not met as evidenced by:

Based on review of SOPs, lack of thermometer calibration records, as well as interview with the TP, the laboratory failed to draft and approve procedures for thermometer calibration and certificate retention. FINDINGS: 1. There was no documentation of calibration or certificate of analysis for the analog thermometers used to monitor the refrigerator and freezer temperatures where patient specimens

were stored. 2. The current, approved SOPs did not include instructions for thermometer calibration and certificate retention. 3. The TP confirmed the findings on August 19, 2025, at approximately 1:00 P.M.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of SOPs, manufacturer's package inserts, temperature and humidity logs, as well as interviews with the LTL and TPs, the laboratory failed to define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting.

FINDINGS: 1. There was no documentation of acceptable temperature or humidity range to indicate if temperatures and humidity were within acceptable limits for the refrigerator, freezer, and room where waived and non-waived test materials were stored, patient specimens processed, and testing performed. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The LTL and TP confirmed the findings on August 19, 2025, at approximately 12:30 P.M.

D5803

TEST REPORT
CFR(s): 493.1291(b)

(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:

Based on lack of patient test records, review of SOPs, as well as interviews with the LTL and TP, the laboratory failed to maintain test report information as part of the patient's medical record. FINDINGS: 1. There was no documentation of patient urine hCG and post vasectomy semen analysis testing. 2. This is contrary to instructions indicated in the current, approved Vasectomy Patients Procedure. 3. The LTL and TP confirmed the findings on August 19, 2025, at approximately 1:45 P.M.