

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1017306	(X3) Date Survey Completed 01/16/2026
Name of Provider or Supplier Georgia Center For Reproductive Medicine	Street Address, City, State 5354 Reynolds Street, Suite 510, Savannah, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification Survey was completed on January 16, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) 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: A review of 2024 - 2026 Quality Control Records and of the Laboratory Procedure Manual confirmed that the laboratory failed to perform quality control testing as stipulated in the Laboratory Procedure Manual. THE FINDINGS INCLUDE: 1. A review of Laboratory Procedure Manual confirmed that there were quality control processes associated with each testing method. The following processes have Quality Control Requirements: a. Basic Semen Analysis Sperm Morphology: QC to be performed each day of testing; b. Basic Semen Analysis Sperm Antibodies - a positive & negative control to be included in each test run; c. Polymorphonuclear Leukocyte Identification: the stain of the Hema 3Stain set is to be evaluated for normal color appearances on slides each day of testing; d. Sperm Wash For Artificial Insemination Procedure: QC performed with each test run 2. An exit interview, with the Laboratory Director and Testing Personnel, on January 16, 2025, at 1:00 pm confirmed that the laboratory failed to perform quality control testing as documented in the Laboratory Procedure Manual.</p>