

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2307801	<b>(X3) Date Survey Completed</b>  05/22/2025
<b>Name of Provider or Supplier</b>  Carolinas Fertility Institute	<b>Street Address, City, State</b>  160, Macgregor Pines Dr Ste 206, Cary, NC	
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>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with Testing Personnel (TP), the laboratory failed to discard expired supplies used for sample collection. Findings: During a tour of the laboratory at approximately 12:45 p.m., the surveyor observed expired materials available for use inside of two cabinets in the phlebotomy area. The following sample collection materials were found: 1. Approximately 30 Becton Dickinson (BD) Vacutainer Serum Separator Tubes (SST), lot 3257998, expiration 2024-09-30 2. Four boxes of Viro/Med Laboratories LabCorp Specialty Testing Group collection kits, lot 10272713, expiration 30Apr2025 During an interview at approximately 1:15 p.m., TP2 confirmed that nurses draw blood and use the phlebotomy supplies for patient samples.</p>
<b>D5473</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2024 and 2025 laboratory quality control (QC) records, lack of documentation and interview with general supervisor</p>

(GS) 05/22/25, the laboratory failed to perform and document QC each day of patient testing for the Nidacon Sperm VitalStain; approximately 6 patients were tested since August of 2024. Findings: Review of laboratory procedure "Viability Staining" revealed "III. Quality Control A. Shake the bottle before use. B. Drop 5 microliters of Vital Stain onto a plain glass slide... . C. ...Search for growth in the stain. D. If no growth is seen, stain is approved for use. ... V. Results A. Dead - Stained red B. Live - unstained...". The procedure fails to include the protocol for the performance of quality control each day of patient testing to ensure the stain is performing as required for the determination of sperm viability. Review of 2024 and 2025 laboratory QC records revealed no documentation of the performance of QC for the Nidacon Sperm VitalStain. Interview with TP2 at approximately 1:30 p.m. confirmed the laboratory does not perform QC for the Nidacon Sperm VitalStain each day of patient testing. They also confirmed the laboratory performed approximately 6 viability stains using the Sperm VitalStain since they opened in August of 2024.