

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2300649	<b>(X3) Date Survey Completed</b>  05/16/2025
<b>Name of Provider or Supplier</b>  Carolinas Fertility Institute	<b>Street Address, City, State</b>  128 Medical Park Road, Suite 103, Mooresville, 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>D5471</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2024 and 2025 quality control (QC) records, lack of documentation, and interview with general supervisor (GS) 05 /16/25, the laboratory failed to perform and document QC for the Waldeck Testsimplets Prestained slides with each new lot number and shipment of slides. Findings: Review of laboratory procedure "Pre-Stain Test-Simplet Morphology Stain Protocol" revealed "Each lot of Test-simplerets should be QC tested upon receipt. QC testing will be performed in Winston-Salem and Greensboro location prior to release to Charlotte, Asheville and Mooresville clinics....". The procedure fails to include the QC requirement for each shipment of slides. Review of 2024 and 2025 QC records for the Waldeck Testsimplets revealed no documentation of the performance of QC by the Mooresville location for each shipment and/or lot number. Interview with GS at approximately at 10:30 a.m. confirmed the Mooresville location does not perform QC for each new lot number or shipment of the Waldeck Testsimplets. They stated they pick up the testsimplets from either Greensboro or Winston-Salem and transport them to their location and the QC was performed by the facility prior to transporting them.</p>
<b>D5473</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</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.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedure, review of 2024 and 2025 laboratory QC records, lack of documentation and interview with GS 05/16/25, the laboratory failed to perform and document QC each day of patient testing for the Nidacon Sperm VitalStain; approximately 2 patients were tested since March of 2024. Findings: Review of laboratory procedure "Viability Staining" revealed "...Solution: Sperm VitalStain...Procedure...a. Mix equal parts of Sperm VitalStain with semen sample. ... f. Count 200 sperm. The white (unstained) are classified as alive and the red or pink are classified as dead. Sperm colored only at the neck region are accessed as alive...4. a. Dead - stained red/purple b. Live - unstained (white) c. The percent viability should be equal to or greater than the percentage of motile sperm.". The procedure fails to include a procedure for the performance of quality control each day of patient testing. Review of 2024 and 2025 laboratory QC records revealed no documentation of the performance of QC for the Nidacon Sperm VitalStain. Interview with GS at approximately 10:30 a.m. confirmed the laboratory does not perform QC for the Nidacon Sperm VitalStain. They also confirmed the laboratory performed 2 viability stains using the Sperm VitalStain since they opened in March of 2024.