

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2315418	(X3) Date Survey Completed 10/10/2025
Name of Provider or Supplier Center Of Reproductive Medicine DbA Shady Grove	Street Address, City, State 121 Vision Park Blvd Ste 215, Shenandoah, TX	
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	An announced survey of the laboratory was conducted on 10/10/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5779	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, sperm morphology quality control (QC) records and staff interview, the laboratory failed to follow its own policy for corrective actions for eleven of eleven instances Sperm Morphology QC was out of the acceptability limits from May through August 2025. Findings included: 1. Review of laboratory's "Verification of Sperm Morphology" (last reviewed 2/1/2025) revealed: "Acceptance Criteria The test is based upon the use of good laboratory technique to achieve a reproducible result within a +/-3." And, "Before reporting any counts that are not within +/- 3 agreement, report the problem to the Supervisor. If applicable, all discrepancies will be properly documented in the comment section." 2. Review of laboratory's "Fertility Solutions Sperm Morphology Daily QC -Strict" logs from May through August 2025 revealed that the log defined acceptable QC as "% Normal = accepted if initial and secondary counts within +/- 3". Further review of the above logs revealed the following counts outside the "+/- 3" acceptability criteria without documentation of corrective action: 2025 Initial Secondary Count day: Count: Count: Difference: June 5A 6 10 4 June 6B 12 17 5 June 11A 6 10 4 June 12B 15 20 5 June 17B 13 20 7 June 19B 18 13 5 June 20B 12 16 4 June 24B 12 18 6 June 26B 14 19 5 July 18B 14 18 4 August 27A 2 6 4 None of the above instances had</p>

documentation for reporting the problem to the Supervisor or annotations in the comment section. 3. In an interview on 10/10/2025 at 1100 hours in the office, the laboratory's Technical Supervisors one and two (as indicated on submitted Form CMS 209) after review of the data confirmed the findings.