

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1092884	(X3) Date Survey Completed 05/05/2025
Name of Provider or Supplier Tennessee Reproductive Medicine, PLLC	Street Address, City, State 6031 Shallowford Road, Suite 101, Chattanooga, TN	
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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of accu-beads manufacturer quality control ranges, review of laboratory procedure, random review of quality control (QC) records, and interview with the general supervisor, the laboratory failed to define the correct QC range for one of two levels of quality control used for manual sperm counts, with unacceptable QC documented for vial one for 49 of 74 days reviewed in 2024 with 387 patient samples tested and reported. The findings include: 1. Observation of the laboratory on 05.05.2025 at 8:45 a.m. revealed a microscope used for patient testing for manual semen analysis and accu-beads quality control vial one (lot number: 240403351, expiration date: 03.2026) and vial two (lot number: 231310181, expiration date: 10.2025). 2. A review of accu-beads manufacturer quality control ranges revealed the following ranges for vial one: fixed coverslip: 35 +/- 5 (30-40) M/ml, and Hemacytometer: 46 +/- 7 (39-53) M/ml. 3. A review of the laboratory's Semen Analysis procedure revealed that it performs manual microscopic analysis for sperm counts using the Makler Chamber (hemacytometer methodology). 4. A random review of the Sperm Count Quality Control logs revealed that the quality control range documented on the QC log was "30 - 40." This range was the incorrect QC</p>

range for the laboratory's methodology. The review also revealed unacceptable QC for 17 of 26 days in May 2024 with 145 patient samples tested and reported, 17 of 24 days in June 2024 with 112 patient samples tested and reported, and 15 of 24 days in July 2024 with 130 patient samples tested and reported. 5. An interview with the general supervisor on 05.05.2025 at 11:30 a.m. confirmed the above survey findings.
Word Key: M/ml = million per milliliter