

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1092884	(X3) Date Survey Completed 08/22/2023
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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: Based on review of the laboratory's procedure manual, the document titled "Andrology Stain Quality Control", patient log for semen analysis with morphology and interview with the practice manger, the laboratory failed to follow policy for documentation of daily stain quality control for 40 of 40 days in 2022. The findings include: 1. Review of the laboratory's Semen Analysis procedure revealed the following statement under the Stain Quality Control section, "Frequency: This process should be performed each day that staining is performed". 2. Review of the document titled "Andrology Stain Quality Control", revealed the following: - No documentation of daily stain quality control from 09.16.2022-09.29.2022 - October 2022 and November 2022: no logs available for surveyor review 3. Review of patient log for semen analysis revealed semen analysis with morphology was performed on the following dates: 09.19.2022, 09.20.2022, 09.21.2022, 09.27.2022, 09.28.2022, 09.29.2022, 10.03.2022, 10.04.2022, 10.05.2022, 10.06.2022, 10.07.2022, 10.10.2022, 10.11.2022, 10.12.2022, 10.13.2022, 10.14.2022, 10.18.2022, 10.19.2022, 10.24.2022, 10.25.2022, 10.26.2022, 10.27.2022, 10.28.2022, 10.31.2022, 11.01.2022, 11.02.2022, 11.03.2022, 11.07.2022, 11.08.2022, 11.09.2022, 11.14.2022, 11.15.2022, 11.16.2022, 11.17.2022, 11.21.2022, 11.22.2022, 11.23.2022, 11.28.2022, 11.29.2022, and 11.30.2022 (40 days total). 4. Interview with the practice manager on 08.30.2023 at 2:45 p.m. confirmed the laboratory failed to follow policy for documentation of daily stain quality control for 40 of 40 days when patient testing occurred in 2022.</p>