

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2284964	(X3) Date Survey Completed 02/10/2026
Name of Provider or Supplier Tristate Men's Health	Street Address, City, State 950 Breckinridge Lane Ste 270, Louisville, KY	
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	A recertification survey was initiated on 02/10/2026 and concluded on 02/10/2026. The facility was found to not be in compliance with laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory procedure manual, and confirmed in staff interview, the laboratory failed to perform an annual RPM (rotations per minute) check on the laboratory's centrifuge for 2 of 2 years (2024, 2025). Findings Included: During a tour of the laboratory area on 02/10/2026 at 10:40 AM, a standard centrifuge, Statspin Express Number 3, was observed for patient preparation. Review of the "General Laboratory Policy and Procedure Manual", Section "General Maintenance", Subsection "Lab Equipment," stated: "If speed or time dependent specimens are obtained, RPM's should be checked annually with a handheld tachometer." No documentation was in place for RPM checks for year 2024 and 2025. In an interview on 02/10/2026 at 12:00 PM in an office room, the Technical Consultant (TC) stated an RPM check had not been performed on the centrifuge. This confirmed the findings.</p>