

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0695435	<b>(X3) Date Survey Completed</b>  01/27/2025
<b>Name of Provider or Supplier</b>  Tulane Medical Center-Andrology	<b>Street Address, City, State</b>  1430 Tulane Avenue, New Orleans, LA	
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>D0000</b>	A Recertification survey was conducted January 27, 2025 at Tulane Medical Center Andrology - CLIA ID # 19D0695435. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.
<b>D2010</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records as well as interview with laboratory personnel, the laboratory failed to test proficiency testing (PT) samples in the same manner as patient testing for three (3) of three (3) events reviewed. Findings: 1. Review of the laboratory's 2023 and 2024 College of American Pathologists (CAP) proficiency testing (PT) records revealed testing personnel attested to performing PT samples as follows: a) SEM-B 2023 Semen Analysis - Testing Personnel 1 and Testing Personnel 2 signed the attestation but did not identify the samples performed b) SEM-A 2024 Semen Analysis - Testing Personnel 1 and Testing Personnel 2 signed the attestation but did not identify the samples performed. c) SEM-B 2024 Semen Analysis - Testing Personnel 1 and Testing Personnel 2 signed the attestation but did not identify the samples performed. 2. Further review of the PT records revealed multiple testing personnel tested each sample as follows: a) SEM-B 2023 Semen Analysis - SEM 11: Tested by Testing Personnel 1, Testing Personnel 2, and a person not listed as Testing Personnel on 11/9/2023 - SEM 12: Tested by Testing Personnel 1, Testing Personnel 2, and a person not listed as Testing Personnel on 11/9/2023 b) SEM-A 2024 Semen Analysis - SEM 01: Tested by Testing Personnel 1, Testing Personnel 2, and a person not listed as Testing Personnel on 4/23/2024 - SEM 02: Tested by Testing Personnel 1, Testing Personnel 2, and a person not listed as</p>

	<p>Testing Personnel on 4/23/2024 c) SEM-B 2024 Semen Analysis - SEM 11: Tested by Testing Personnel 1 on 10/24/2024, Testing Personnel 2 on 10/24/2024 and 10/30/2024, and a person not listed as Testing Personnel on 10/29/2024 - SEM 12: Tested by Testing Personnel 1 on 10/24/2024, Testing Personnel 2 on 10/24/2024 and 10/30/2024, and a person not listed as Testing Personnel on 10/29/2024 3. In interview on January 27, 2025 at 10:39 a.m., the Laboratory Director stated patient samples are tested by one personnel only. He further stated the three (3) personnel identified above tested all the samples and he took the average of all the results obtained for each sample and submitted the average to the CAP PT program.</p>
<p><b>D5217</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's patient test records and proficiency testing (PT) records as well as interview with personnel, the laboratory failed to verify the accuracy of performance for sperm morphology and motility testing at least twice per year in 2023 and 2024. Findings: 1. Review of the following randomly selected patient final test report revealed the laboratory performed the following testing for semen analysis: a) MRN: 1002497275 - Composition and count - Sperm motion - Sperm morphology 2. Review of 2023 and 2024 PT records revealed the laboratory performed twice a year verification of sperm count testing, but did not perform morphology and/or motility. 3. In interview on January 27, 2025 at 11:26 a.m., the Laboratory Director stated the laboratory reports sperm morphology and motility in addition to sperm counts, but the clinicians utilize the count. He confirmed the laboratory did not perform twice per year verification for sperm morphology and motility testing as identified above.</p>
<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>(a) 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 policy and procedure manual and interview with personnel, the laboratory failed to establish a complete policy and procedure for proficiency testing. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have complete policies for Proficiency Testing (PT) to include but not limited to the following: - Testing and resulting PT samples in the same manner as patient samples - Twice a year verification for testing in which the laboratory is not enrolled in a PT program - Corrective action for unacceptable PT results 2. In interview on January 27, 2025 at 11:26 a.m., the Laboratory Director confirmed the laboratory did not have a policy for PT as identified above.</p>
<p><b>D6087</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b></p>

	<p>CFR(s): 493.1445(e)(3)(iii)</p> <p>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5217.</p>
<p><b>D6089</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2010.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.</p>