Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0695435	04/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Tulane Medical Center-Andrology	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was performed on April 6, 2023 at Tulane Andrology, CLIA ID # 19D0695435. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with personnel, the laboratory failed to ensure the Laboratory Director and Testing Personnel signed the proficiency attestation statement for one (1) of three (3) proficiency testing (PT) events. Findings: 1. Review of the College of American Pathologists (CAP) proficiency testing records revealed the attestation statement was not signed by the Laboratory Director and Testing Personnel for Semen Analysis event Sem-A 2022. 2. In interview on April 6, 2023 at 10:56 a.m., the Laboratory Director confirmed the attestation for the event identified was not signed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with laboratory

	personnel, the laboratory failed to review the performance evaluation for three (3) of three (3) proficiency testing events reviewed. Findings: 1. Review of the College of American Pathologists (CAP) proficiency testing records revealed the laboratory did not review the evaluations for the following proficiency testing events for Semen Analysis: Sem-B 2021 Sem-A 2022 Sem-B 2022 2. In interview on April 6, 2023 at 10:56 a.m., the Laboratory Director confirmed the evaluations were not signed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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. This STANDARD is not met as evidenced by: I. Based on review of patient test records and the laboratory's policy and procedure manual, as well as interview with personnel, the laboratory failed to follow their policy for repeat sperm count testing. Findings: 1. Review of the laboratory's policy "Patient Sample Sperm Count SOP" revealed the following: -Tulane Andrology Lab performs duplicate testing on patient manual sperm counts utilizing Leja 20 micron 2 chamber slide system. -If the percentage difference between the two values is less than or equal to 15%, an average of the two readings should be calculated to obtain the mean value of the counts. -If the percentage difference between the two readings is greater than 15%, the technician should repeat the analysis with a 3rd drop of sample and record the value for the 3rd drop. -After counting the 3rd drop, the median of the three readings should be reported as a final count result. 2. Review of the "Tulane Andrology Laboratory - Quality Assessment Q/C Sperm Count" patient record from September 21, 2022 revealed the following results for one (1) of one (1) patients tested that day: Patient LG2-9/22 Drop 1 = 42.3 Drop 2 = 50.3 (Surveyor calculation of percent difference = 19%) 3. Further review of the "Tulane Andrology Laboratory - Quality Assessment Q/C Sperm Count" record for September 21, 2022 revealed the laboratory did not repeat the sample with a third drop. 4. In interview on April 4, 2023 at 11:16 AM, the Laboratory Director confirmed although the patient results identified above had a greater than fifteen percent difference between the two counts, a third drop was not performed. II. 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 manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have complete policies for: a) Proficiency Testing (PT) to include but not limited to: * Ensuring that you are enrolled for Proficiency Testing. *What documents need to be signed and who needs to sign them. *What records to maintain. *How to evaluate your scores from the PT Provider. *Who needs to document review of the PT scores. *What steps to take if corrective action is needed. b) Expired items 2. In interview on April 6, 2023 at 12:45 p.m., the Laboratory Director confirmed they did not have the policies identified above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with laboratory personnel, the laboratory failed to ensure that pipet tips were not used beyond their expiration date. Findings: 1. Observation by surveyor during the laboratory tour on April 6, 2023 at 9:58 AM revealed the following expired items: a) VWR disposable sterile pipet tips for most 200 uL pipettors; 1-200 uL expiration date 2021-02 Lot batch 40434-806C4-806AL b) VWR disposable sterile pipet tips for most 200 uL pipettors; 1-200 uL expiration date 2019-06 Lot batch 40080-626C4-626AL 2. In interview on April 6, 2023 at 9:58 AM, the Laboratory Director confirmed the items listed above were expired.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test records and the laboratory's policy and procedure manual, as well as interview with personnel, the laboratory failed to ensure quality control results met the laboratory's acceptability criteria prior to reporting patient test results for four (4) of thirty-one (31) days of patient testing reviewed. Findings: 1. Review of the laboratory's procedure titled "Quality Control Sperm count SOP" revealed the following: -Tulane Andrology Lab must perform one level of Q/C sperm Count each eight hours of patient's semen evaluation by assessing sperm counts in duplicates, in a minimum of six grids of 20 micron Leja Slides. -After performing the count, calculate % difference. If the (H-L)/L *100 = > +/- 15%, perform the procedure a third time. 2. Review of "Quality Assessment Q/C Sperm Count Form" records revealed the following quality control results had a greater than 15% percent difference as calculated by the surveyor; however, a third drop was not performed. a) July 11, 2022 - Drop 1 = 33.3 Drop 2 = 27.3 (Surveyor calculation of percent difference = 22%); one (1) patient tested b) July 13, 2023 - Drop 1 = 28.5 Drop 2 = 34.5 (Surveyor calculation of percent difference = 21%); one (1) patient tested c) September 19, 2022 Drop 1 = 30.1 Drop 2 = 36.6 (Surveyor calculation of (percent difference = 22%); one (1) patient tested d) September 26, 2022 Drop 1 = 32.8 Drop 2 = 27.4 (Surveyor calculation of percent difference = 20%); two (2) patients tested 3. In interview on April 6, 2023 at 11:16 AM, the Laboratory Director confirmed that although the quality control values identified above had a greater than fifteen percent difference, a third drop was not performed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on observation; review of laboratory policies, quality control and patient test records; as well as interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in the Analytic system. Findings: 1. Review of quality control and patient test records indicated problems with the analytic system as follows: a) The laboratory failed to follow their policy for sperm count testing. Refer to D5401 I. b) The laboratory failed to ensure that pipet tips were not used beyond their expiration dates. Refer to D5417. c) The laboratory failed to ensure quality control results were acceptable prior to reporting patient test results for five (5) of thirty-one (31) days of patient testing reviewed. Refer to D5481. 2. The laboratory had a Quality Assurance policy "Q/C Evaluation and Quality Assurance Guidelines;" however, the laboratory failed to identify the issues cited above. 3. In interview on April 6, 2023 at 12:45 p.m., the Laboratory Director confirmed the Quality Assessment process in place did not identify the problems in the analytic system.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5791.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure that pipet tips were not used beyond their expiration dates. Refer to D5417. 2. The laboratory failed to follow their policy for repeat sperm count testing. Refer to D5401 I.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)

	The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. 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 D2009.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the proficiency testing evaluations were reviewed. Refer to D5211.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of patient test records and the laboratory's policy and procedure manual, as well as interview with personnel, the Laboratory Director failed to ensure that the laboratory took corrective action when quality control values were unacceptable. Refer to D5481.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. 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 responsible for any aspect of the testing process. Refer to D5401 II.