

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0695435	(X3) Date Survey Completed 12/12/2018
Name of Provider or Supplier Tulane Medical Center-Andrology	Street Address, City, State 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 Certification Survey was performed on December 12, 2018 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.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to label solutions utilized for manual semen analysis with expiration dates and storage requirements. Findings: 1. Observation by surveyor during laboratory tour on December 12, 2018 revealed the following solutions in smaller containers without expiration dates and storage requirements included on the label: a) Quick III Solution I b) Morphology Staining Fixative 2. In interview on December 12, 2018 Personnel 2 stated he pours the solutions from the larger bottles into smaller containers for use. Personnel 2 stated the smaller containers are labeled with the solution name.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the laboratory failed to ensure control material has not exceeded its expiration date. Findings: 1. Observation by surveyor during laboratory tour on December 12, 2018 revealed the following expired items: a) Quality Control (QC), Lot number: 16070, Quantity: one (1) vial b) QC, Lot number: 16080, Quantity: one (1) vial 2. Review of the laboratory's quality control records revealed the identified quality control material was prepared April 25, 2016. 3. In interview on December 12, 2018, Personnel 1 stated QC expires two years from preparation date. Personnel 1 stated the identified QC was old.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) 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, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to label solutions utilized for manual semen analysis with expiration dates and storage requirements. Refer to D5415. 2. The laboratory failed to ensure control material has not exceeded its expiration date. Refer to D5417.