

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2044520	(X3) Date Survey Completed 08/15/2018
Name of Provider or Supplier Center For Advanced Reproductive Services	Street Address, City, State 4 Shaws Cove, Ste # 201, New London, CT	
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
D2011	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3)</p> <p>Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, proficiency testing (PT) samples were being used as internal blind samples for assessing competency of testing personnel (TP) prior to submitting to the PT program due date in the specialty of hematology. Findings include: 1. Record review of the College of American Pathologists (CAP) PT records on 8/15/18 revealed 1 of 3 TP would perform the PT samples and submit the results. The other 2 of 3 TP performed the same PT samples as internal blind samples prior to the CAP PT program due date for the following surveys: a) SPCD-A in 2017, 2 of 3 TP performed on 5/9/17, PT due date was 5/16/17. b) SPCD-B in 2017, 2 of 3 TP performed on 11/29/17, PT due date was 12/5/17. c) SPCD-A in 2018, 2 of 3 TP performed on 5/9/18, PT due date was 5/16/18. 2. Record review of the laboratory's "Internal Audit Andrology" procedure #20189-021 on 8/15/18 revealed "previously submitted/analyzed CAP PT sperm count DVD's are used for internal audit testing ONLY after official PT results have been submitted". 3. Interview with the technical supervisor on 8/15/18 at 10:05 AM confirmed 2 of 3 TP performed PT samples as internal blind samples prior to the CAP PT program due date for the above surveys. 4. The laboratory performs 360 semen analysis tests annually.</p>

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:

Based on record review and staff interview, testing personnel (TP) failed to follow written policies and procedures in the specialty of hematology. Findings include: 1. Record review of the laboratory's "Internal Audit Andrology" procedure #2018-021 on 8/15/18 revealed "previously submitted/analyzed CAP PT sperm count DVD's are used for internal audit testing ONLY after official PT results have been submitted" 2. Record review of the TP competency records on 8/15/18 revealed 2 of 3 TP performed PT as blind samples prior to the "official PT results being submitted" per the laboratory procedure for the following: a) SPCD-A 2017 PT samples were tested on 5/9/17, official results were submitted on 5/11/17. b) SPCD-B 2017 PT samples were tested on 11/29/17, official results were submitted on 11/30/17. c) SPCD-A 2018 PT samples were tested on 5/9/18, official results were submitted on 5/11/18. 3. Staff interview with the technical supervisor (TS) on 8/15/18 at 10:30 AM confirmed the laboratory failed to follow their procedure. The TS further stated the procedure should reflect the PT due date not the submission date. 4. The laboratory performs 360 semen analysis tests annually.

D6136

CLINICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1457

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Record review of the laboratory's personnel competency records on 8/15/18 revealed the following: a) The laboratory did not have a policy in place to assess the competency of the clinical consultant. b) Competency documentation for the above laboratory personnel was not available. 2. Staff interview with the laboratory technical supervisor on 8/15/18 at 11:00 AM confirmed the above findings.