

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2113679	(X3) Date Survey Completed 06/05/2019
Name of Provider or Supplier Advanced Reproductive And Urologic Procedures	Street Address, City, State 7200 Cambridge Room B10,609, Houston, TX	
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from 2017 to 2019 and staff interview, it was revealed the laboratory failed to have a method in place to</p>

monitor quality control values over time and evaluate accuracy and precision over time. Findings included: 1. A review of the laboratory's quality control records from March of 2017 to May of 2019 for 9 analytes ran on the Beckman DXi 600 analyzer, revealed the laboratory failed to have a method in place for monitoring and evaluating quality control results over time. A. The 9 analytes run on the Beckman DXi 600 include: 1. Follicle Stimulating Hormone (FSH) 2. Luteinizing Hormone (LH) 3. Testosterone 4. Estradiol 5. Dehydroepiandrosterone sulfate (DHEA-S) 6. Prostate Specific Antigen (PSA) 7. Free- PSA 8. Prolactin 9. Sex Hormone Binding Globulin (SHBG) 2. The laboratory was asked to provide documentation of monitoring and evaluating control values. No documentation was provided. 3. An interview with the laboratory director on 6/5/19 at 12:10 in the laboratory revealed the laboratory only assessed qc values each day and did not monitor or evaluate values over time for shifts or trends. This confirmed the above findings.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of the lab's personnel records and staff interview it was revealed the technical consultant failed to ensure competency assessments were performed at least semiannually for 1 of 3 testing personnel. Findings included: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 6/4/19) revealed the labroatory identified 3 testing personnel. 1. A review of the laboratory's personnel files revealed testing personnel #2 as listed on CMS 209 form was hired 3 /2017. Based on this date, testing personnel #2 should have had at least 2 competency assessments performed prior to 3/2018. 2. Further review of the laboratory personnel records revealed the technical consultant performed a competency assessment for testing personnel #2 on 2/17/19. 3. The laboratory was asked to provide documentation of the 2 competency assessments prior to 3/2018. No documentation was provided. 4. An interview with the technical consultant on 6/5/19 at 10:15 in the conference room confirmed the above findings.