Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2045259	09/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Urology Department (Mfa)	7321 Hanover Pkwy Suite A, Greenbelt, MD	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview with chemistry laboratory (lab) staff, the lab did not ensure that proficiency testing records are maintained. Findings: 1. The lab did not maintain the testing records performed for proficiency testing (PT) challenges performed in 2018 and 2017 including work records, intermediate test records, attestation sheets and printouts of test results for the prostatic acid phosphatase (PSA) tests performed on the proficiency test samples; and 2. These findings were confirmed during interview of lab staff at approximately 10:30 am on the day of survey.
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 record review and interview with chemistry laboratory (lab) staff, the lab did not ensure that proficiency testing results are reviewed by the lab director . Findings: 1. The lab did not maintain the evaluations performed for proficiency testing (PT) challenges by the PT provider in 2018 and 2017 including the directors signed review of the report; and 2. These findings were confirmed during interview of lab staff at approximately 10:30 am.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on record review and interview with chemistry laboratory (lab) staff, the laboratory written procedure was incomplete did not include control and calibration procedures. Findings: 1. The quality control procedure for prostatic acid phosphatase (PSA) testing did not include instructions for the number of quality control reagents (control levels) tested and the frequency of testing. During interview with lab staff at approximately 10:00 am staff stated that two levels of control are tested each day of patient testing; 2. The quality control procedure did not include instructions for the lab to use either the World Health Organization recommendations for acceptable quality control ranges or the Hybridtech recommendations as published by the manufacturer; 3. The written procedure did not include instructions for the lab to test the two calibrators at least every 30 days and with each change in lot number of reagent test packs or lot number of controls; and 4. These findings were confirmed during interview of lab staff at approximately 10:30 am. B. Based on record review and interview with chemistry laboratory (lab) staff, the technical consultant did not ensure that the lab has written procedures for completing the Daily Environmental Log . Findings: 1. The lab staff records their initials within the Run QC row in the Daily Environmental Log ; 2. The initials are there as a quick check showing controls were tested; 3. The lab written procedures did not define what test kits or tests are indicated in the quality control column as being performed; and 4. These findings were confirmed during interview of lab staff at approximately 10:30 am.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with lab staff, the lab director did not ensure that a corrective action plan was approved by the director and followed when unacceptable proficiency test results were reported to the lab by the proficiency test provider. Findings: 1. The lab is enrolled in a proficiency test program for prostatic acid posphatase (PSA) testing (chemistry); 2. The proficiency test provider sends the lab unknown samples to test and report. The reported test results are graded for accuracy by the provider, as the provider compares the labs responses to other labs using similar test methods; 3. The lab obtained unsatisfactory test scores for the first test event in 2018 and the second event in 2017. This means that the lab has failed two of three proficiency test events for the PSA test; 4. The lab director did not investigate the failure in 2018 and did not investigate the failure in 2017 and did not provide a written corrective action plan to ensure that the testing is accurate and reliable; and 5. This was confirmed during interview with lab staff on the day of survey.
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 record review and interview with chemistry laboratory (lab) staff, the technical consultant did not ensure that competency checks are performed 6 months and 12 months after the initial training is completed. Findings: 1. The lab performed a prostatic acid phosphatase (PSA) test on a patient sample on September 11, 2018, prior to this date, the last patient test was performed in September 2016; 2. The technical consultant did not have written procedures to check competency of testing persons 6 months and 12 months after the initial training is completed; and 3. These findings were confirmed during interview of lab staff at approximately 10:30 am.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interview with chemistry laboratory (lab) staff, the

	technical consultant did not ensure that competency checks are performed annually for testing persons. Findings: 1. The lab performed a prostatic acid phosphatase (PSA) test on a patient sample on September 11, 2018, prior to this date, the last patient test was performed in September 2016; 2. The technical consultant did not have written procedures to check competency of testing persons annually; 3. The technical consultant did not have records showing that competency checks were performed in 2017; and 4. These findings were confirmed during interview of lab staff at approximately 10:30 am on the day of survey.