

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2045259	(X3) Date Survey Completed 08/16/2021
Name of Provider or Supplier Urology Department (Mfa)	Street Address, City, State 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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 09/24/2018 for not ensuring that all the proficiency testing (PT) records were maintained. The plan of collection stated that the records would be maintained for the required amount of time. Based on review of the PT records for prostate specific antigen (PSA) and interview with the testing person, the laboratory failed to maintain all required PT documentation. Findings: 1. The PT records from 2019 through the second event of 2021 (7 events) were reviewed. 2. The PT records for the first event in 2021 were not available for review. 3. The PT records from the third event in 2019 failed to include the original instrument printout and the attestation worksheet. 4. The PT review records from 2019 (3 events), 2020 (3 events) show that the laboratory directors signature stamp was present, but no date of review was documented to show that the records were reviewed in a timely manner. 5. The PT attestation worksheet from the 3rd event of 2020 failed to include the signature and</p>

date of the LD. 6. During the survey on 08/16/2021 at 12:30 PM, the testing person confirmed that the PT documents were not maintained as required and dated as required to ensure that reviews were performed in a timely manner.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and interview, the laboratory director failed to ensure that the QA reviews were performed by a qualified person (minimum educational requirement of a bachelor's degree and 2 years documented experience), failed to document the fact that the PT samples had not been submitted on time to the PT agency for the second event of 2021, and failed to ensure that the PT records were maintained (D6021); and failed to ensure that all policies and procedures followed in the laboratory were approved (D6031).

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
I. Based on review of the quality assessment (QA) records and interview with the testing person, the laboratory director (LD) acting as the technical consultant (TC) failed to ensure that the QA reviews were performed by a qualified person (minimum educational requirement of a bachelor's degree and 2 years documented experience) and were reviewed by the LD on a monthly basis. Findings: 1. The monthly "QA checklist" worksheets (31 months) for 2019, 2020, and 2021 were reviewed. The worksheets require documentation that the following policies were followed: "Laboratory Safety Policies", "Personnel Policies", "Proficiency Testing Policies", "Pre and Post Analytic Systems", "Quality Control Policies", "Quality Assurance Program", and "Maintenance Program." 2. The worksheets require documentation of the "Date", "Test Analyst" and "Lab Director" signatures each month. The "Test Analyst" section was signed by a person who was not qualified as the TC on 29 of 31 QA checklists reviewed and 2 of 31 checklists had no documented review at all. The testing person confirmed that the testing personnel who signed the section labeled "Test Analyst" did not have a four year degree. 3. The LD failed to document the review of 13 of 31 QA checklists. 4. The LD failed to include the date of the review to ensure that the worksheets were reviewed in a timely manner on 31 of 31 worksheets. 5. During the survey on 08/16/2021 at 12:30 PM, the testing person confirmed that the person who signed the section labeled "Test Analyst" on the QA checklist did not qualify as the TC, the checklist were not all signed and approved by the LD, and the

QA checklist did not include the date when the LD reviewed the worksheet. II. Based on review of the "QA checklist" for July 2021 and interview with the testing person, the LD acting as the TC failed to document the fact that the PT samples had not been submitted on time to the PT agency for the second event of 2021. Findings: 1. The section labeled "Our Proficiency Testing Policies have been followed:" on the July 202 checklist included a check mark indicating that the following was acceptable: "Proficiency test results were evaluated, failures were investigated, and remedial action was taken." 2. The "Performance Review And Corrective Action" section of the PT performance evaluation worksheet for "2021 Chemistry - Core - 2nd Event" stated that the PT had been performed but not entered before the deadline. 3. The failure was not identified on the QA checklist, the evaluation of the incident was not documented by the LD acting as the TC, and there was no mention of what would be implemented to prevent this from happening in the future. 4. During the survey on 08/16/2021 at 12:30 PM, the testing person confirmed that the PT incident was not documented on the QA checklist and there was no mention of what would be implemented to prevent this from happening in the future. III. Based on review of the proficiency testing (PT) records and interview with the testing person, the laboratory director (LD) acting as the technical consultant (TC) failed to ensure that the PT records were maintained. Cross refer to D2015 for details.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) 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 review of the procedure manual and interview with the testing personnel, the new laboratory director failed to ensure that all policies and procedures followed in the laboratory were approved (signed and dated). Findings: 1. Review of the procedure manual showed that the procedures were not approved (signed and dated) by the current laboratory director. 2. During the survey on 08/16/2021 at 12:30 PM, the testing person confirmed that the procedures manuals were not signed and dated by the current laboratory director.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of the competency documentation and interview with the teasing personnel, the laboratory director (LD) acting as the technical consultant (TC) failed to perform and document the competency review on all testing personnel. Findings: 1. The laboratory currently has four testing personnel listed on the "Laboratory

Personnel Report (CLIA) (CMS-209)". 2. The laboratory records failed to include annual competencies for the testing personnel for 2019 and 2020. The annual competencies for 2021 only included documentation for 2 of the four testing personnel listed on the CMS-209. 3. During the survey on 08/16/2021 at 12:30 PM, the testing person confirmed that the evaluations for 2019 and 2021 were not available at the time of the survey.