

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0930860	(X3) Date Survey Completed 09/25/2018
Name of Provider or Supplier Regional Urology	Street Address, City, State 2539 Viking Drive, Suite 105, Bossier City, 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 at Regional Urology, LLC - CLIA # 19D0930860 on September 25, 2018. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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: Based on record review and interview with personnel, the laboratory failed to ensure that proficiency testing (PT) documents were signed by the appropriate personnel. Findings: 1. Review of the laboratory's PT records revealed the attestation statements for the 2018 Chemistry - Miscellaneous - 1st Event were signed by the Laboratory Director only. The Testing Personnel did not sign all PT documents. 2. In interview on September 25, 2018 at 4:15 pm, Personnel 3 stated she forgot to sign the attestation statement for that PT event. Personnel 2 confirmed the statement was not signed by the testing personnel.</p>
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Technical Consultant were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 serves as the Technical Consultant. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of Technical Consultant which includes the frequency of assessment performance. 3. Review of personnel records revealed competency assessments for the duties of Technical Consultant were not documented. 4. In interview on September 25, 2018 at 4:15 pm, Personnel 2 stated the policy and competency assessment for her duties as Technical Consultant was at another location and she was unaware that both forms need to be at each site that she serves as Technical Consultant. Personnel 2 confirmed documentation was not available for the above.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to label urine specimens per laboratory policy. Findings: 1. Review of the laboratory's policy and procedure manual revealed the following information: a) Policies for Collecting, Labeling, Handling, and Storing Specimens: Specimens are collected, labeled, and handled in a manner to optimize patient test results by ensuring that specimens are not mixed-up, mislabeled or deteriorated. b) Specimen Collection and Labeling Procedures -- Identify the patient: Identify patients by having them (or a guardian) state their full name and date of birth. -- Select appropriate collection supplies -- Label Collection tubes: Label all tubes with the patient's full name, date of birth, KREDO number and collector's initials. 2. In interview on September 25, 2018 at 1:24 pm, Personnel 3 stated blood and urine samples are labeled with patient's full name, date of birth, and specific identifier to patient. Personnel 3 further stated urine samples are collected by the patients and brought to the nurse who places the samples on a paper in the laboratory that has the room number where the patient is located. 3. Direct observation by surveyor on September 25, 2018 during laboratory tour revealed the following: a) Patient 9 labeled with patient's last name with first name initial and date of birth placed on paper in laboratory under Room 1 b) Patient 10 labeled with patient's last name and date of birth placed on paper in laboratory under Room 2 c) Patient 11 with no identification placed on paper in laboratory under Room 3 d)

Patient 12 labeled with patient's first and last name and date of birth placed on paper in laboratory under Room 4 4. In interview on September 25, 2018 at 1:24 pm, Personnel 3 confirmed the urine samples were not identified correctly.

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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D5311.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance. Refer to D2015.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Refer to D5311.