

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1069363	(X3) Date Survey Completed 08/27/2019
Name of Provider or Supplier Middle Tennessee Urology Specialists	Street Address, City, State 1747 Medical Center Parkway Suite #210, Murfreesboro, TN	
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: Based on a review of proficiency testing (PT) record's attestation statements for 2018-2019 and an interview with the lead lab nurse, the laboratory failed to ensure two of seven testing persons (TP)/ analysts performing the hematology urine sediment examination (USE) PT events' specimens signed the attestation statements in 2019. Findings include: 1. There were no TP/analysts signatures for 2 of 7 TP analysts for PT 1st and 2nd events 2019 for USE specimens from 2018-2019 available to review. 2. In an interview, August 27, 2019, at 10:30am, the lead lab nurse confirmed the missing 2 of 7 TP#3 & TP#5 analyst's signatures on the attestation statements for the hematology urine sediment examination PT 1st and 2nd events 2019.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p>

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of the laboratory quality assessment (QA) procedure, the 2018 and 2019 proficiency testing (PT) records and interview with the lead lab nurse, the laboratory failed to verify the accuracy of Microscopy urine sediment examination by a First Unsuccessful Performance) in 2018. The findings include: 1. Review of the QA procedure revealed no procedure for verifying the urine sediment examination accuracy twice a year. 2. Review of the 2018-2019 PT records revealed the laboratory failed to achieve successful performance (First Unsuccessful Performance) in Hematology for Microscopy in Urine Sediment Examination (USE) analytes in Event Two in 2017 and Event One in 2018. 3. Interview on August 27, 2019 at 10:45 am with the lead lab nurse confirmed the laboratory failed to achieve successful performance (First Unsuccessful Performance) in Hematology for Microscopy in Urine Sediment Examination (USE) analytes in Event Two in 2017 and Event One in 2018.

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 a review of the laboratory's performance of moderate complex testing, the laboratory director failed to ensure: proficiency testing (PT) samples were tested correctly (Refer to D6016) and testing person (TP#1) education documents were available (Refer to D6029) in 2018-2019.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) records and an interview with the lead lab nurse, the laboratory director failed to ensure PT samples were tested the same number of times that it routinely tests patient samples for urine sediment examination and semen analysis in 2018-2019. Findings include: 1. Review of the PT records revealed 2 testing persons (TP) reported the PT results for urine sediment examination and semen analysis when only one TP reports patient resulted for the same tests in 2018-2019. 2. In an interview, on August 27, 2019, at 10:30am, the lead lab nurse

confirmed that 2 TPs were reporting PT events for Chemistry (Urine Sediment Examination) and Hematology (Semen Analysis) and only one TP reported patient test results for the same tests listed for 2018-2019.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, testing person (TP) records and an interview with the lead lab nurse, the laboratory director failed to ensure TP education verification documents for one of seven TP were available for 2018-2019. Findings include: 1. Review of the CMS 209 personnel form revealed seven testing persons performing moderate complexity testing (MCT) for 2018-2019. 2. Review of 1 of 7 TP records revealed no education documents for TP#1 (i.e. high school diploma/transcript) for 2018-2019. 3. An interview on August 27, 2019, at 10:15am, with the lead lab nurse confirmed the laboratory did not have any education documents available for review on TP#1 for 2018-2019.

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 employee personnel records and interview with the lead tech, the laboratory's technical consultant failed to document the six required criteria for assessing personnel competency for 5 of 5 testing persons (TP) in 2018-2019. The findings include: 1) Review of 5 of 5 employee personnel records for 2018-2019 did not reveal documentation of the six required criteria of competency that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills for urine sediment examination and semen analysis. 2) An interview with the lead tech on August 27, 2019 at 10:30am confirmed 5 of 5 testing personnel evaluated during 2018 and 2019 were not evaluated using the six criteria for competency required by Centers for Medicare and Medicaid (CMS).

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 a review of the laboratory's employee competency evaluations and upon interview with the lead tech, determined the Technical Consultant failed to perform and document a semi-annual competency evaluation for testing personnel #2 who began laboratory testing in June of 2018. The findings include: 1. A review of the laboratory's semi-annual competency evaluation results were not available for testing person #2 of who began patient testing for Chemistry (Prostate Specific Antigen - PSA) on June 10, 2018. 2. An interview with the lead tech at approximately 10:00 am on August 27, 2019, confirmed that no semi-annual competency evaluation was documented for testing person #2 since the hire date in June of 2018.