

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315440	(X3) Date Survey Completed 06/11/2018
Name of Provider or Supplier West Tn Univ Med Associates	Street Address, City, State 294 Summar Dr, Jackson, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing attestation statements and interview with testing personnel number one, the laboratory director failed to sign attestation statements for 2017 events one and three. The findings include: 1. Review of the laboratory's proficiency testing attestation statements for 2017 events one and three revealed no signature by the laboratory director. 2. Interview with testing personnel number one on June 11, 2018 at 3:00 pm confirmed that the laboratory director failed to sign the attestation statements for 2017 events one and three.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy titled "Personnel Competency" and interview with testing personnel number one, the laboratory failed to establish policies for competency assessment of testing personnel as specified in subpart M. The findings include: 1. Review of the laboratory's policy titled "Personnel Competency" revealed that testing personnel competency is documented by proficiency testing,</p>

annual evaluations, checklist, color blind test, and employee position description questionnaire. 2. Interview with testing personnel number one on June 11, 2018 at 10:30 am confirmed that the laboratory's policy for testing personnel competency assessment was not in compliance with Subpart M. The required elements include: Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem solving skills. Evaluating and documenting the performance of individual responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed annually.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on review of the laboratory's proficiency testing evaluation report for 2017 event two, review of the laboratory's policy titled "Quality Assurance Plan," and interview with testing personnel one, the laboratory failed to verify the accuracy of non-graded proficiency testing results for urine sediment and vaginal wet prep for 2017 event two. 1. Review of the laboratory's proficiency testing evaluation report for 2017 event two revealed the following samples were scored as "Pass" with a comment code of "Not Graded-Lack of Referee Consensus" for sample numbers CM-12 and CM-13 for urine microscopy and sample number CM-15 for vaginal wet prep. The report was signed by both the laboratory director and the technical consultant. 2. Review of the laboratory's policy titled "Quality Assurance Plan" revealed that evaluation of non-graded proficiency testing results was not included. 3. Interview with testing personnel number one on June 11, 2018 at 11:00 am confirmed that the laboratory failed to verify the accuracy of non-graded proficiency testing results for sample numbers CM-12, CM-13, and CM-15 for 2017 event two.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's form used for documenting review of complete blood count (CBC) quality control data, the laboratory's quality assurance plan, and interview with testing personnel number one, the technical consultant failed to ensure the quality control program was maintained in 2016 and 2017. The findings include:

1. Review of the form used for documenting technical consultant review of CBC quality control data revealed no signature for review of quality control data for dates 11.7.2016 to 11.23.2016 and 7.22.2017 to 8.28.2017.
2. Review of the laboratory's quality assurance plan revealed the following statement "We will evaluate our quality control program for calibration and control data for each test method used in the lab and determine: a. If calibrators and controls are run according to written policy and procedures; b. If personnel have taken appropriate corrective action when calibration or control values are out of the acceptable range;"
3. Interview with testing personnel number one on June 11, 2018 at 3:00 pm confirmed that the technical consultant failed to review CBC quality control data in 2016 and 2017 and failed to ensure the quality control program was maintained.