

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1105124	(X3) Date Survey Completed 08/12/2019
Name of Provider or Supplier Madison Family Practice	Street Address, City, State 621 G-Old Hickory Blvd, 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 proficiency testing records, and interview with the laboratory liaison, the laboratory director / designee failed to sign the proficiency testing attestation statement for 2019 event one hematology/urine sediment. 1) Review of the laboratory's proficiency testing records revealed the attestation statement for hematology/urine sediment 2019 event one was not signed by the laboratory director or designee. 2) Interview with the laboratory liaison on August 12, 2019 at 12:15 pm confirmed the proficiency testing attestation statement for hematology/urine sediment 2019 event one was not signed.</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records, the laboratory</p>

procedure manual, and interview with the laboratory liaison, the laboratory director failed to ensure the laboratory had a procedure for performing corrective action for unacceptable proficiency testing scores in 2019. 1) Review of the laboratory proficiency testing performance evaluation report for 2018 event three for hematology /urine sediment revealed a score of "Fail" for sample number HD-12 for lymphocyte %. No corrective action had been performed for the unacceptable score. 2) Review of the laboratory procedure titled "Proficiency Testing" revealed that corrective action for unacceptable proficiency testing scores was not included in the procedure. 3) Interview with the laboratory liaison on August 12, 2019 at 12:15 pm confirmed the laboratory director failed to ensure the laboratory had a procedure for performing corrective action for unacceptable proficiency testing scores in 2019.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of the laboratory procedure manual, and interview with testing personnel number three, testing personnel number three failed to follow procedure for performing urine microscopic exam in 2019. The findings include: 1) Observation of the laboratory on August 12, 2019 at 8:40 am revealed a microscope on the counter in use for patient testing for urine microscopy. 2) Review of the laboratory procedure for urine microscopy revealed the following: "Centrifuge the 12 ml of urine at 3000 RPMs for 3 minutes." "A drop of the suspension is then placed on the slide for examination." 3) Interview with testing personnel number three on August 12, 2019 at 11:00 am revealed the following: a timer is not used when centrifuging the urine samples for urine microscopy; 2 drops of urine are placed on the slide for examination. Testing personnel number three confirmed testing personnel number three did not follow the procedure for urine microscopy in 2019.