

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1011560	(X3) Date Survey Completed 02/07/2019
Name of Provider or Supplier Katherine W Jones Md Plc	Street Address, City, State 40 West Caldwell Street Suite 100, Mount Juliet, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Test attestation records for Hematology Complete Blood Count testing (CBC) and an interview with the lead testing person the Technical Consultant failed to ensure proficiency testing samples are performed by personnel who routinely perform CBC testing in 2018. The Findings include: 1. Review of the proficiency testing attestation records revealed the Technical Consultant failed to ensure proficiency testing samples are performed by personnel who routinely perform CBC testing in 2018. 2. Interview with the lead testing person on February 7, 2019 at 12:30 confirmed the Technical Consultant failed to ensure proficiency testing samples are performed by personnel who routinely perform CBC testing in 2018.</p>
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</p>

system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of Proficiency Test records for Hematology Complete Blood Count testing (CBC) and an interview with the lead testing person the Technical Consultant (TC) failed to ensure the laboratory retain a copy of proficiency testing records for the 3rd event 2017; signed attestation statements for the 2nd event 2017 and 1st event 2018 and signed Performance Evaluations for 2nd event 2017 and the 2nd and 3rd event 2018. The findings include: 1. Review of the proficiency testing records revealed the Technical Consultant failed to maintain copies of proficiency testing records for the 3rd event in 2017; have signed attestation statements for the 2nd event 2017 and 1st event 2018 and failed to sign the performance evaluations for the 2nd event 2017 and 2nd and 3 event 2018. 2. Interview with the lead testing person on February 7, 2019 at 12:30 confirmed the Technical Consultant failed to maintain copies of proficiency testing records for the 3rd event in 2017; signed attestation statements for the 2nd event 2017 and 1st event 2018 and signed performance evaluations for the 2nd event 2017 and 2nd and 3 event 2018.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on lack of record review of analyzer verification performance specifications for the Horiba Complete Blood Count (CBC) Analyzer and interview with the lead testing person the laboratory failed to verify the performance specifications after relocation of the CBC analyzer in August 2017. The Findings include: 1. Lack of record review of analyzer verification performance specifications for the Horiba CBC Analyzer revealed the laboratory failed to verify the performance specifications after relocation of the CBC analyzer in August 2017. 2. Interview with the lead testing person on February 7, 2019 at 12:45 confirmed the laboratory failed to verify the performance specifications after relocation of the CBC analyzer in August 2017.

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 testing personnel Semi-Annual and Annual competency

evaluations forms and interview with the lead testing person the Technical Consultant (TC) failed to evaluate 3 or 4 testing personnel annual competencies for Hematology Complete Blood Count (CBC) test in 2018. The Findings include: 1. A review of the testing personnel Semi-annual and Annual competency evaluation forms for Hematology CBC testing revealed the Technical Consultant failed to perform 3 of 4 testing personnel annual competency evaluations in 2018. 2. Interview with the lead testing person on February 7, 2019 at 12:40 confirmed the Technical Consultant failed to perform 3 of 4 testing personnel's annual competency evaluations for Hematology CBC testing in 2018.

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 review of testing personnel Semi-Annual and Annual Competency evaluations forms and interview with the lead testing person the Technical Consultant (TC) failed to evaluate 4 or 4 testing personnel semi-annual competencies for Hematology Complete Blood Count (CBC) test in 2018. The Findings include: 1. A review of the testing personnel Semi-Annual and Annual Competency evaluations forms for Hematology CBC testing revealed the Technical Consultant failed to perform 4 of 4 testing personnel semi-annual competency evaluations in 2018. 2. Interview with the lead testing person on February 7, 2019 at 12:45 confirmed the Technical Consultant failed to perform 4 of 4 testing personnel's semi-annual competency evaluations for Hematology CBC testing in 2018.