

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0689203	<b>(X3) Date Survey Completed</b>  05/08/2018
<b>Name of Provider or Supplier</b>  Ruth C Schobel Md Pa	<b>Street Address, City, State</b>  7480 Fairway Dr Ste 202, Miami Lakes, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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, the laboratory failed to maintain copies of attestation statements for their proficiency testing from 5/8/2016 to 5/8/2018. Findings include: The laboratory is enrolled in proficiency testing with American Proficiency Institute (API) for hematology. Review of the laboratories proficiency testing records showed that the laboratory didn't have any attestations statements for proficiency testing for 2016 2nd and 3rd events, 2017 1st, 2nd and 3rd events, and 2018 1st event. Review of the laboratory's procedure "Proficiency Testing" showed that the procedure states the attestation statement will be printed and signed by the testing personnel and the laboratory director. During an interview on 5/8/18 at 10:50 AM, Testing Personnel C stated that she had never seen any attestation statements with their proficiency paperwork.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p>

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document that the results of proficiency scores were reviewed from 5/8/2016 to 5/8/2018. Findings include: Review of the laboratories proficiency testing records showed that the laboratory directory didn't sign the "Proficiency Testing Performance Evaluation" form for proficiency testing for 2016 2nd and 3rd events, 2017 1st, 2nd and 3rd events, and 2018 1st event. Review of the laboratory's procedure "Proficiency Testing" showed that the procedure states that the laboratory director reviews it, initials and dates it. During an interview on 5/8/18 at 10:52 AM, Laboratory Director stated that she had reviewed the proficiency testing results but failed to sign the forms.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to follow their policy to conduct a semi annual quality assurance reviews for 2016 and 2017. Findings Included: Review of the "Goals of our Quality Assurance Program" policy, states that quality assurances reviews will be performed every 6 months and written records will be kept. At the time of the survey no records of quality assurance reviews were documented. During an interview on 5/8/18 at 11:55 AM Laboratory Directory confirmed that the semi annual quality assurance reviews were not documented.

**D6054**

**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 annually, after the first year.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document the competency performance of testing personnel for 2016 and 2017. Findings include: Review of laboratory competency records showed that there were no competency records for testing personnel A, B, and C listed on the "Laboratory Personnel Report" (form CMS-209) for 2016 and 2017. Review of the laboratory's procedure manual in the section titled "Personnel Assessment" states that the laboratory director will review the performance of each employee working in the laboratory at least annually. During an interview on 5/8/18 at 11:55AM, Laboratory Director acknowledged that competency was observed and evaluated but was not documented.