

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0982582	<b>(X3) Date Survey Completed</b>  10/08/2018
<b>Name of Provider or Supplier</b>  Sharon Mitchell Medical Clinic Llc	<b>Street Address, City, State</b>  13 Village Plaza, Liberal, KS	
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 a review of lab policies and procedures, proficiency testing (PT) records during calendar years 2017 and 2018 through the PT provider, American Proficiency Institute (API) and staff interview, the laboratory failed to document each step in the testing and reporting of results for all proficiency test samples. Findings were: 1. A review of the laboratory's proficiency API records showed the Laboratory Director and Testing Person's failed to sign the Attestation Statement for the following testing events: Hematology/Coagulation - 2018: 1st and 2nd events Chemistry Core - 2018: 1st and 3rd events; 2017: 1st event Microbiology - 2018: 1st, 2nd, and 3rd events; 2017: 1st event Immunology/Immunochemistry - 2018: 1st and 2nd events: 2017: 3rd event 2. This was confirmed with interview with testing personnel #2 (refer to Testing Personnel Report (CMS-209)) at 4:14 PM on October 8, 2018.</p>
<b>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</p>

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's analyzer maintenance records and interview with staff, the laboratory failed to perform maintenance and function checks for the Frend analyzer, Horiba analyzer, rotator, microscope, and centrifuges as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings Include: 1. Review of Frend preventative maintenance (PM) records found at the time of the survey, the last documented maintenance occurred November 2016 with no documented maintenance in 2017 or 2018. 2. Review of the Horiba PM records found at the time of the survey, only cleaning had been documented and no other maintenance for 2017 or 2018. 3. Review of rotator PM records, used for the rheumatoid factor test, found no function checks or maintenance records for 2017 or 2018. 4. Review of PM records at the time of the survey, found no procedure or documentation of maintenance for the microscope for 2017 and 2018. 5. Review of PM records at the time of the survey, found no procedure or documentation of maintenance / tachometer checks for centrifuges for 2017 or 2018. 6. The above findings were verified by interview with the testing personnel (refer to Testing Personnel Report (CMS-209)) at 4:17 pm and 5:09 pm on October 8, 2018 in the laboratory.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Review of package inserts, 2017 and 2018 quality control records, and interview with staff, the laboratory failed to perform the quality control required by the manufacturer and per laboratory policy. Findings were: 1. Review of package insert for Sure-Vue RF (Rheumatoid Factor) states "Before performing a set of determinations it is advisable to check the latex reagent with each of the controls, positive and negative, included in the kit." 2. Review of the laboratory's procedure for RF states "run quality control prior to any testing of patient sample." 3. Review of RF quality control log has documented QC performed only once per month for 2017 and 2018. 4. The above findings were confirmed by interview with testing personnel #2 (refer to Testing Personnel Report (CMS-209)) at 4:52 pm on October 8, 2018.