

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 17D0448313	<b>(X3) Date Survey Completed</b> 01/15/2020
<b>Name of Provider or Supplier</b> Drs Heidgen & Mills Office	<b>Street Address, City, State</b> 3550 S 4th St, Suite 120, Leavenworth, 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>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p> <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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documents and interview, the laboratory failed to establish and follow a routine accuracy check for the thermometers. Findings: 1. Request was made for accuracy check records for the two thermometers used in the laboratory. No documentation was made available at the time of survey. 2. Interview with the Laboratory Director on January 15, 2020 at 9:30 a.m. confirmed, the laboratory failed to establish and follow a routine accuracy check for the thermometers.</p>
<b>D6053</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of competencies and interview, the Technical Consultant (TC) failed to evaluate and document competency at least semiannually during the first year the</p>

individual tests patient specimens for one of three testing personnel. Findings: 1. Review of personnel competency records revealed no semiannual competency for testing personnel (TP) #2. 2. Interview with the TC on January 15, 2020 at 10:00 a.m. confirmed, the technical consultant failed to evaluate and document competency at least semiannually during the first year the individual tests patient specimens for one of three testing personnel.