

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2091838	(X3) Date Survey Completed 04/09/2018
Name of Provider or Supplier Rm Lab DbA Express Lab	Street Address, City, State 444 Hospital Way, Bldg 100 #224, Pocatello, ID	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical supervisor, the laboratory failed to establish and document the competency assessment for the technical supervisor since the last survey on April 11, 2016. Findings: 1. A review of personnel documents and laboratory procedures and policies, revealed the laboratory failed to establish in writing and document the competency for the technical supervisor listed on the CMS-209 Personnel Report form. 2. An interview on April 9, 2018 at 1:30 PM, with the technical supervisor, confirmed the laboratory failed to establish and assess the competency for the technical supervisor since the last survey.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical supervisor, the laboratory failed to verify the accuracy of parathyroid hormone (PTH) at least twice annually since the last survey on April 11, 2016. Findings: 1. A record review of proficiency testing from American Proficiency Institute and the laboratory's testing reports for PTH, revealed the laboratory failed to document the accuracy of PTH at</p>

least twice annually since the last survey on April 11, 2016. 2. An interview on April 9, 2018 at 3:45 PM, with the technical supervisor, confirmed the laboratory failed to document the accuracy of PTH at least twice annually.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on a record review and an interview with the technical supervisor, the laboratory failed to establish and document unscheduled maintenance and corrective actions for the Ortho Vitros 5.1, Beckman Coulter AcT Diff, and the Siemens Immulite 2000 for since the last survey in April 11, 2016. Findings: 1. A record review of the laboratory procedures revealed the laboratory failed to establish a corrective action procedure for documenting when maintenance activities are performed on the analyzers in the lab since the last survey. 2. An interview on April 9, 2018 at 3:30 PM, with the technical supervisor, confirmed the laboratory failed to establish and document corrective actions for the analyzers maintenance.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a record review and an interview with the technical supervisor, the laboratory testing person A failed to follow the manufacturer's instructions for quality control performance on the Beckman Coulter AcT Diff 5 complete blood count (CBC) analyzer on April 5, 2017. Findings: 1. A record review of calibration and quality controls for the AcT Diff CBC analyzer on April 5, 2017, revealed that testing person A failed to perform quality control after calibration of the analyzer as required by the manufacturer before reporting patient CBC results. 2. An interview on April 9, 2017 at 3:00 PM, with the technical supervisor, confirmed testing person A failed to perform quality control testing after calibration performance before reporting patient CBC results.