

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0980387	(X3) Date Survey Completed 05/02/2023
Name of Provider or Supplier Ip Boise 1	Street Address, City, State 8660 W Emerald St #102, Boise, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from the American Proficiency Institute (API) and an interview with the technical supervisor (TS) on 5/2/2023, the laboratory failed to document the evaluation of PT results for the specialty of hematology. The findings include: 1. A review of PT documents for the specialty of hematology from API identified that the laboratory failed to document the evaluation of unacceptable PT results for monocytes (sample COU-14) for event three (3) in 2022. 2. An interview with the TS on 5/2/2023 at 10:03 am confirmed that the laboratory failed to document the evaluation of PT results for hematology event three (3) in 2022. 3. The laboratory reports performing 158,997 hematology tests annually.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation from the American Proficiency Institute (API) and an interview with the technical supervisor (TS) on 5/2</p>

/2023, the laboratory failed to evaluate the accuracy of analytes that were assigned an artificial score of 100% because they were ungraded by the PT provider. The findings include: 1. A review of hematology PT documentation from API for 2022 event three (3) identified that the laboratory failed to evaluate the following ungraded samples: blood cell identification: BCI-14; nucleated red blood cell: COU-12; sperm classification: SCL-11, SCL-12, SCL-15, SCL-16 and sperm morphology: SM-03, SM-04. 2. An interview with the TS on 5/2/2023 at 10:03 am confirmed that the laboratory did not evaluate the accuracy of ungraded PT results that were given an artificial score of 100%. 3. The laboratory reports performing 158,997 hematology tests annually.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on a review of maintenance records for the Beckman Coulter AU680, Roche Cobas E601, Stago Satellite and an interview with the technical supervisor (TS) on 5/2 /2023, the laboratory failed to perform instrument maintenance as required by the manufacturer. The findings include: 1. A review of maintenance records for the Beckman Coulter AU680 identified that the laboratory failed to complete quarterly maintenance which included replacing the ISE pinch valve tubing from May to December of 2022. 2. A review of maintenance records for the Roche Cobas E601 identified that the laboratory failed to complete quarterly maintenance which included replacing the ISE pinch valve tubing and every six months clean inlet water filter and cooling fans May to December of 2022. 3. A review of maintenance records for the Stago Satellite identified that the laboratory failed to complete quarterly maintenance which included replacing the air filters in May and November 2022 and yearly replace the needle in August of 2022. 4. An interview with the technical supervisor on 5/2 /2023 at 3:31 pm confirmed the above maintenance had not been performed. 5. The laboratory reports performing 439,134 tests annually.