

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2047419	(X3) Date Survey Completed 09/13/2023
Name of Provider or Supplier Raise The Bottom	Street Address, City, State 9196 W Barnes St, 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
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 review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, CMS 116 application form, training and competency assessment records and an interview with the laboratory director on 9/13/2023, the laboratory failed to follow written policies and procedures to assess testing personnel training and competency in 2022 and 2023. The findings include: 1. A review of the CMS 209 identified two (2) testing personnel performing moderate and high complexity toxicology testing. 2. A review of the CMS 116 identified a new testing system (Beckman Coulter AU480) for performing moderate complexity toxicology testing. 3. A review of training and competency assessment records identified two (2) of two (2) testing personnel failed to have initial training for the for Beckman Coulter AU480 documented. 4. A review of competency assessment records identified one (1) of two (2) testing personnel failed to have a six month competency for the Beckman Coulter AU480 documented in 2022. 5. A review of competency assessment records identified one (1) of two (2) testing personnel failed to have an annual competency for the Beckman Coulter AU480 documented in 2023. 6. An interview with the laboratory director on 9/13/2023 at 1:30 pm confirmed the above findings. 7. The laboratory reports performing toxicology testing on 29,000 urine specimens annually.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the</p>

laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of laboratory procedures, a lack of documentation and an interview with the technical supervisor (TS) on 9/13/2023, the laboratory failed to follow its procedure for centrifuge maintenance for 2022 and 2023. The findings include: 1. The laboratory procedure; "Laboratory Standard Operating Procedure, RTB SOP #3 Eppendorf 5430 Centrifuge" states to clean the centrifuge weekly and to calibrate every six months. 2. A lack of documentation for the Eppendorf 5430 Centrifuge identified that the laboratory failed to perform and document weekly cleaning and semiannual calibration. 3. An interview with the TS on 9/13/2023 at 3:50 pm confirmed that the laboratory failed to perform and document weekly cleaning and semiannual calibration of the centrifuge. 4. The laboratory reports performing toxicology testing on 29,000 urine specimens 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 laboratory maintenance logs and an interview with the technical supervisor (TS) on 9/13/2023, the laboratory failed to perform maintenance on the Beckman Coulter AU480 as defined by the manufacturer, with at least the minimum specified frequency. The findings include: 1. A record review of the Beckman Coulter AU480 maintenance logs identified that the laboratory failed to perform monthly maintenance as required by the manufacturer for 10 of 12 months in 2022 and 8 of 8 months in 2023. A review of the maintenance logs on the analyzer confirmed these findings. 2. An interview with the TS on 9/13/2023 at 3:32 pm confirmed the above findings. 3. The laboratory reports performing toxicology testing on 29,000 urine specimens annually.