

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2032859	(X3) Date Survey Completed 05/17/2024
Name of Provider or Supplier Rehabilitative Health Services Medical Clinic	Street Address, City, State 1675 Curlew Dr, Ammon, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from the American Association of Bioanalysts (AAB) and an interview with the laboratory lead on 5/17/2024, the laboratory failed to sign PT attestations for 2022, 2023 and 2024. The findings include: 1. A review of PT records from AAB for events one and two in 2023 identified that the testing personnel failed to sign the attestation statements for complete blood count (CBC) testing. 2. A review of PT records from AAB for event three in 2023 identified that the laboratory director and testing personnel failed to sign the attestation statement for CBC testing. 3. A review of PT records from AAB for event one in 2024 identified that the laboratory director and testing personnel failed to sign the attestation statement for CBC testing. 4. An interview with the laboratory lead on 5/17/2024 at 9:32 am confirmed that the laboratory director and testing personnel failed to sign attestation statements for the above events. 5. The laboratory reports performing 17,750 hematology tests annually.</p>
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:</p>

Based on a review of proficiency testing (PT) records from the American Association of Bioanalysts (AAB) and an interview with the laboratory lead on 5/17/2024, the laboratory director failed to review PT results for 2023. The findings include: 1. A review of PT records from AAB for events two and three in 2023 identified that the laboratory director failed to review and evaluate graded results for complete blood count (CBC) testing. 2. An interview with the laboratory lead on 5/17/2024 at 9:32 am confirmed that the laboratory director failed to review and evaluate the graded PT results in 2023. 3. The laboratory reports performing 17,750 hematology tests annually.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on a lack of documentation for the verification of accuracy for urine drug screen testing and an interview with the laboratory lead on 5/17/2024, the laboratory failed to ensure accuracy at least twice annually in 2023. The findings include: 1. A lack of verification of accuracy documentation for urine drug screen testing identified that the laboratory failed to ensure testing accuracy twice in 2023 for the following analytes: Alcohol, Fentanyl, Tramadol, amphetamine, buprenorphine, benzodiazepine, cocaine, ecstasy, methamphetamine, opiate, methadone, oxycodone and marijuana. 2. An interview with the laboratory lead on 5/17/2024 at 10:52 am confirmed the above finding. 3. The laboratory reports performing 31,850 toxicology tests annually.

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:
Based on a lack of quality control (QC) performance documentation for urine drug screen testing and an interview with the laboratory lead on 5/17/2024, the laboratory failed to ensure accurate test results each day of patient testing. The findings include: 1. A lack of QC documentation for urine drug screen testing identified that the laboratory failed to perform QC for the following analytes: alcohol, Fentanyl, Tramadol, amphetamine, buprenorphine, benzodiazepine, cocaine, ecstasy, methamphetamine, opiate, methadone, oxycodone and marijuana each day of patient testing 2. An interview with the laboratory lead on 5/17/2024 at 10:52 am confirmed the above finding. 3. The laboratory reports performing 31,850 toxicology tests annually.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on a lack of documentation for the verification of performance specifications for urine drug screens and an interview with the laboratory lead on 1/17/2024, the technical consultant failed to ensure test performance specifications were established and verified before beginning patient testing. The findings include: 1. A lack of documentation for the verification of performance specifications for urine drug screen testing identified that the laboratory failed to verify precision, accuracy and reportable range for the following analytes: Alcohol, Fentanyl, Tramadol, amphetamine, buprenorphine, benzodiazepine, cocaine, ecstasy, methamphetamine, opiate, methadone, oxycodone and marijuana. 2. An interview with the laboratory lead on 5/17/2024 at 10:52 am confirmed the above finding. 3. The laboratory reports performing 31,850 toxicology tests annually.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory procedures, training and competency assessment records and an interview with the laboratory lead on 5/17/2024, the technical consultant (TC) failed to follow policies and procedures to assess testing personnel (TP) competency. The findings include: 1. The CMS 209 identified six (6) testing personnel (TP) performing complete blood count (CBC) testing. Four (4) of the six (6) TP have start dates after the previous inspection on 6/23/2022. 2. A review of training and competency assessment records identified that the laboratory failed to have annual competency assessments for complete blood count (CBC) testing for three (3) of three (3) TP in 2023. 3. A review of training and competency assessment records identified that the laboratory failed to have six month competency assessments for CBC testing for two (2) of two (2) TP in 2023. 4. An interview with the laboratory lead on 5/17/2024 at 9:05 am confirmed the TC failed to perform competencies in 2023. 5. The laboratory reports performing 17,750 hematology tests annually.