

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0056438	(X3) Date Survey Completed 11/07/2024
Name of Provider or Supplier Lost Rivers Medical Center	Street Address, City, State 551 Highland Dr, Arco, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from the Wisconsin State Laboratory of Hygiene (WSLH) and an interview with the laboratory manager on 11/7/2024, the laboratory director or designee failed to sign PT attestations in 2023 and 2024. The findings include: 1. A review of PT documents from WSLH for 2023 identified that the laboratory director or designee failed to sign the attestation statements for chemistry/endocrinology/toxicology event two and three, hematology event three, blood gas event three and immunology event three. 2. A review of PT documents from WSLH for 2024 identified that the laboratory director or designee failed to sign the attestation statements for microbiology event one, blood gas event one, immunohematology event one, coagulation event one, chemistry/endocrinology/toxicology event two, blood gas event two and immunology event three. 3. An interview with the laboratory manager on 11/7/2024 at 9:30 am confirmed that the laboratory director or designee failed to sign the above attestation statements. 4. The laboratory reports performing 279,013 tests annually.</p>

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 the Cepheid GeneXpert maintenance logs and an interview with the laboratory manager on 11/7/2024, the laboratory failed to perform quarterly maintenance as required by the manufacturer in 2023 and 2024. The findings include: 1. A review of Cepheid GeneXpert maintenance logs identified that the laboratory failed to perform the quarterly maintenance (disinfection of the cartridge bay interior and the plunger rod) three of four quarters in 2023 and three of four quarters in 2024 as required by the manufacturer. 2. An interview with the laboratory manager on 11/7/2024 at 12:58 pm confirmed that quarterly disinfection of the Cepheid GeneXpert was not performed as required by the manufacturer. 3. The laboratory reports performing 1,140 tests annually on the Cepheid.

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (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) records and an interview with the laboratory manager on 11/7/2024, the laboratory failed to successfully perform two levels of QC each day of use for the Ortho Vitros 5600 in 2022. The findings include: 1. A lack of QC documents for the Ortho Vitros 5600 on 12/27/2022 identified that the laboratory failed to perform at least two levels of QC for each chemistry, endocrinology and immunology analyte on 12/27/2022. 2. A review of patient testing records from 12/27/2022 identified 43 patient samples tested on the Ortho Vitros 5600. 3. An interview with the laboratory manager on 11/7/2024 at 11:44 am confirmed that there was no QC for the 43 patient samples tested on 12/27/2022. 4. The laboratory reports performing 208,810 tests on the Ortho Vitros 5600 annually.

D5551

IMMUNOHEMATOLOGY

CFR(s): 493.1271(a)(f)

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.

(f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a record review of immunohematology quality control (QC), patient test reports and an interview with the laboratory manager on 11/7/2024, the laboratory failed to document control results for immunohematology testing in 2023. The findings include: 1. A review of immunohematology QC for 2023 and 2024 identified that the laboratory failed to document QC on 3/8/2023 for ABO grouping, Rh typing, and unexpected antibody detection. 2. A review of patient test reports identified ABO grouping, Rh typing, and unexpected antibody detection was performed on one patient (203135) on 3/8/2023. 3. An interview with the laboratory manager on 11/7/2024 at 3:53 pm confirmed the above findings. 4. The laboratory reports performing 123 immunohematology tests annually.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on a lack of documentation and an interview with the laboratory manager on 11/7/2024, the laboratory failed to evaluate results for chemistry analytes performed on multiple analyzers to ensure the allowed acceptable difference between analyzers. The findings include: 1. A lack of documentation for analyte result comparison between the laboratory's Ortho Vitros 5600 and 350 analyzers identified that the laboratory failed to evaluate test results for alanine transaminase (ALT), albumin, alkaline phosphatase (ALP), aspartate aminotransferase (AST), bilirubin, BUN (blood urea nitrogen), calcium, carbon dioxide (bicarbonate), chloride, creatinine, glucose, potassium, sodium and total protein to ensure that they were within the allowed acceptable difference between the two analyzers every six months in 2023 and 2024. 2. An interview with the laboratory manager on 11/7/2024 at 11:01 am confirmed that the laboratory failed to compare analyte results between analyzers to ensure accurate patient testing. 3. The laboratory reports performing 208,810 tests annually on the Vitros analyzers.