

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D1076417	(X3) Date Survey Completed 08/15/2024
Name of Provider or Supplier Mountain View Redicare	Street Address, City, State 2730 Channing Way, Idaho Falls, 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
D0000	During an offsite paper revisit the laboratory was found to be in compliance with the CLIA regulations (42 CFR Part 493 effective April 24, 2003.) No deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of temperature records, patient records and an interview with the technical consultant (TC) on 8/15/2024, the laboratory failed to document temperatures and humidity as required for operation of the Sysmex XP-300. The findings include: 1. A review of the manual for the Sysmex XP-300 identified an operational temperature of 15-35 C and an operational humidity of 20-80%. 2. A review of the laboratory's daily temperature records identified that the laboratory failed to document room temperature and humidity since the last inspection (3/9 /2023). 3. An interview with the TC on 8/15/2024 at 2:20 pm confirmed that the laboratory fail to document temperatures and humidity. 4. The laboratory reports performing 1,142 complete blood count tests annually.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p>

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 review of Quality Control (QC) records, patient records and an interview with the technical consultant (TC) on 8/15/2024, the laboratory failed to perform two levels of QC daily with complete blood count (CBC) testing on the Sysmex XP-300 in 2023. The findings include: 1. A random review of laboratory QC documents identified that the laboratory failed to have two levels of QC for CBC testing on the Sysmex XP-300 on 3/29/2023 and 3/30/2023. 2. A review of patient records identified two (2) patients (03230880020, 03230880005) that had CBC testing performed on 3/29/2023 and four (4) patients (03230890134, 03230890180, 03230890294, 03230890295) that had CBC testing performed on 3/30/2023. 3. An interview with the TC on 8/15/2024 at 3:03 pm confirmed the above findings. 4. The laboratory reports performing 1,142 CBC tests annually.