Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2106190	03/31/2026
Name of Provider or Supplier	**Street Address, City, State**	
Aspen Mountain Medical Center	4401 College Drive, Rock Springs, WY	

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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel records, lack of documentation, review of policy and procedures, and staff interview, the laboratory failed to ensure the competency of the staff member holding the position of general supervisor was assessed for 2 of 2 years reviewed (2024, 2025). The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed the laboratory listed one staff member as the general supervisor. 2. Review of the personnel records for the general supervisor showed no evidence a competency assessment had been completed in 2024 or 2025. 3. Review of the "Employee Competency Evaluation" policy, last revised 6 /2025, failed to include a procedure to assess the duties of the general supervisor. 4. Interview with the general supervisor on 3/31/26 at 11 AM confirmed no further documentation was available and the policy did not include a procedure for assessing the competency of the general supervisor.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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).

	This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, staff interview, and review of policy and procedure, the laboratory failed to review proficiency test results that received an artificial score of 100% due to result variance for 1 of 24 American Proficiency Institute (API) proficiency testing events reviewed from January 2024 through December 2025. The findings were: 1. Review of the 2025 API Chemistry Event #3 proficiency testing comparative evaluation form showed the laboratory received an artificial score of 100% for the analyte of total bilirubin. There was no documentation the laboratory had performed a self-evaluation. 2. Interview with the general supervisor on 3/31/26 at 10:30 AM confirmed an evaluation of the proficiency testing results had not been evaluated for accuracy. 3. Review of the "PROFICIENCY TESTING" policy, last revised 6/2025, showed "...If PT [proficiency testing] challenges were not graded because of 1) lack of consensus, Scientific Decision, or Educational challenge...the laboratory will compare and evaluate each result with the PT booklet and findings are documented. For other exception reason codes that signify the proficiency testing (PT) for an analyte has not been graded. The exception reason code is located on the evaluation report in brackets to the right of the results. Therefore the laboratory must identify all of the analytes with exception reason code with the same rigor as if it were an unacceptable performance..."
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on new instrument and new test method verification study review, lack of documentation, review of policy and procedure, review of patient testing logs, and staff interview, the laboratory failed to verify the reportable range and confirm the manufacturer's normal values were appropriate for the laboratory's patient population prior to patient testing for 1 of 1 (Alcor miniiSED) verification studies reviewed. The laboratory performed seven erythrocyte sedimentation rate (ESR) patient tests from 2/2/26 through 3/30/26. The findings were: 1. Review of the new instrument and new test method verification study failed to show documentation the laboratory had verified the reportable range and had confirmed the reference intervals used for the test system were appropriate for the laboratory's population. The laboratory director approved the verification study on 2/15/26. 2. Review of the patient testing log showed ESR testing on the Alcor miniiSED commenced on 2/2/26. 3. Review of the "ESR-ALCOR Mini-i-Sed" policy and procedure showed it was approved by the laboratory director in March of 2026. 4. Interview with the general supervisor on 3/31/26 at 11:58 AM confirmed no further documentation was available. 5. Review of the "VERIFICATION OF PERFORMANCE SPECIFICATIONS AND NOTIFICATION OF CURRENT LABORATORY METHODS" policy and procedure, last revised 6

	/2025, showed "Verification of Performance Specifications are required prior to reporting patient test results on any unmodified, FDA-cleared or approved non-waived test system (i.e., moderate and high complexity) introduced into the laboratory...the laboratory is required to verify the following: 1. Accuracy 2. Precision 3. Reportable range of patient test results (comparable to the manufacturer's) 4. Reference intervals/range (normal values) for the Laboratory's patient population..."
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory director failed to conduct at least two onsite visits to the laboratory for 1 of 1 year reviewed (2025). The findings were: 1. Review of the laboratory's records showed no evidence the laboratory director had made an onsite visit to the laboratory in 2025. Interview with the general supervisor on 3/31/26 at 8:30 AM confirmed the laboratory director had not been onsite and revealed she was unaware of the regulation.