Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2106190	01/04/2022
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) evaluation reports and staff interview, the laboratory failed to successfully participate in two consecutive API chemistry core proficiency testing events for sodium, potassium, and chloride (2021 event #2, 2021 event #3). Refer to D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two

	consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) evaluation reports and staff interview, the laboratory failed to successfully participate in two consecutive API chemistry core proficiency testing (PT) events for sodium, potassium, and chloride (2021 event #2, 2021 event #3). The findings were: 1. Review of the API chemistry core PT evaluations showed the laboratory failed to successfully obtain a passing score for the analyte of sodium on the following API testing events: a. 2021 event #2 showed 3 of the 5 specimens tested were not graded due to a "lab reported test problem". b. 2021 event #3 showed 4 of the 5 specimens tested were not graded due to a "lab reported test problem". 2. Review of the API chemistry core PT evaluations showed the laboratory failed to successfully obtain a passing score for the analyte of potassium on the following API testing events: a. 2021 event #2 showed 3 of the 5 specimens tested were not graded due to a "lab reported test problem". b. 2021 event #3 showed 3 of the 5 specimens tested were not graded due to a "lab reported test problem". 3. Review of the API chemistry core PT evaluations showed the laboratory failed to successfully obtain a passing score for the analyte of chloride on the following API testing events: a. 2021 event #2 showed 3 of the 5 specimens tested were not graded due to a "lab reported test problem". b. 2021 event #3 showed 4 of the 5 specimens tested were not graded due to a "lab reported test problem". 4. Review of the PT corrective action report for the 2021 event #2 showed the laboratory had contacted the manufacturer's field representative to troubleshoot the problem and determined the failure was due to a possible proficiency testing sample issue. There was no documentation the laboratory had followed-up on the failure. 5. Review of the PT corrective action report for the 2021 event #3 showed the laboratory had noted the "electrolytes were still having issues" and the manufacturer's field representative was contacted. The laboratory reviewed the instrument's quality control and patient samples and determined the failure was due to a possible proficiency sample issue. There was no documentation the laboratory had followed-up on the failure. 6. Interview with the laboratory manager on 1/4/22 at 2:15 PM confirmed the laboratory had not investigated the unsuccessful PT events to determine the root cause of the failure.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 review of the Siemens EXL SARS-CoV-2 Total Antibody new test method verification study, policy and procedure review, and staff interview, the laboratory failed to verify precision prior to testing patient samples. The laboratory performed 51 patient tests from 9/16/20 to 1/4/22. The findings were: 1. Review of the Siemens

	EXL SARS-CoV-2 Total Antibody new test method verification study completed on 9 /16/20 showed the performance specification of precision had not been verified. In addition there was no evidence the laboratory director had reviewed the verification study documentation and approved the test procedure prior to testing patient samples. 2. Interview with the laboratory manager on 1/4/22 at 2:15 PM confirmed the verification study was incomplete. 3. Review of the policy and procedure titled "Validation and Notification of current Laboratory Methods" last approved 4/2020 showed "...In order to validate method under the new guidelines the lab has to demonstrate that the instrument can obtain performance specifications comparable to those claimed by the manufacturer. The studies to be performed are: Precision /imprecision study: Precision is established by repeat measurement of samples at varying concentrations or activities within run and between run over a period of time... Validation checklist...Signature of Medical Director approving the use of Test /Method."
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Siemens EXL SARS-CoV-2 Total Antibody test verification documentation, review of proficiency testing evaluation reports, policy and procedure review, and staff interview, the laboratory director failed to ensure the test verification study was complete and had approved the testing procedure for SARS-CoV-2 Total Antibody prior to testing patient samples (D6086) and failed to ensure an effective corrective action plan was developed to prevent reoccurrence of the failed analytes of sodium, potassium, and chloride for 2 consecutive API chemistry core proficiency testing events (2021 event #2, event #3 (D6092).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the Siemens EXL SARS-CoV-2 Total Antibody test verification documentation, policy and procedure review, and staff interview, the laboratory director failed to ensure the test verifications of accuracy, precision, analytic specificity, and analytic sensitivity was complete and met the laboratory's performance characteristics specified by the manufacturer. Refer to D5421.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) evaluation reports and staff interview, the laboratory director failed to ensure an effective corrective action plan was developed to prevent reoccurrence of the failed analytes of sodium, potassium, and chloride for 2 consecutive API chemistry core proficiency testing events (2021 event #2, 2021 event #3). Refer to D2096.