Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0652478	(X3) Date Survey Completed 08/11/2025
Name of Provider or Supplier Roosevelt Medical Center	**Street Address, City, State** 818 2nd Avenue East, Culbertson, MT	

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	A proficiency testing desk review was completed on August 11, 2025. During the desk review, it was determined that the laboratory was not in compliance with all conditions required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 Code of Federal Regulations, Part 493 (42 C.F.R. 493). The following condition-level deficiency was cited: 493.803 Condition: Successful participation.
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 an off-site review of the CMS-155 reports of proficiency testing performance, American Proficiency Institute (API) proficiency testing (PT) scores, corresponding laboratory records, and email communication with the technical

	supervisor (TS) #1, the laboratory failed to achieve satisfactory performance for toxicology for two consecutive testing events. This resulted in unsuccessful proficiency testing performance in 2025. See D2118
D2118	TOXICOLOGY CFR(s): 493.845(f) (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 a review of American Proficiency Institute (API) proficiency testing (PT) scores, laboratory records, and email communication with the technical supervisor (TS) #1, the laboratory failed to achieve a score of at least 80% for two consecutive proficiency testing events for alcohol in 2025. Findings: 1. A review of API's Chemistry Toxicology PT scores and laboratory records for alcohol on August 11, 2025, revealed that the laboratory failed to achieve a satisfactory performance score of 80% or greater for the following PT events: 2025, Event 1: scored 60% 2025, Event 2: scored 0% 2. An email from TS #1 on August 1, 2025, at 7:48 PM confirmed the two consecutive failed 2025 PT events for the analyte alcohol. The failures were due to a random error in Event 1 and a failure to submit results for Event 2.