Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0658954	10/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Faith Community Health Center	112 North 2nd Avenue West, Faith, SD	

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 recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 10/19/23. Faith Community Health Center laboratory was found not in compliance with the following requirements: D5215.
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 record review and interview, the laboratory failed to review proficiency testing (PT) results to ensure their accuracy for one of five PT events reviewed (American Proficiency Institute [API] Hematology/Coagulation 2022 third event). Findings include: 1. Review on 10/19/23 at 10:10 a.m. of the laboratory's PT records revealed: *The cutoff date for returning the laboratory's PT results for the API Hematology/Coagulation third testing event was 11/23/22. *The Medonic hematology analyzer was shipped to the manufacturer for repairs. *The laboratory had been unable to process the PT samples. *The laboratory reported "Instrument Out of Service" for all 14 reportable analytes. *The performance summary for the testing event had been available for review on 12/12/22. *The following 14 reportable analytes had been scored "ungraded"- leukocyte (white blood cell) count erythrocyte (red blood cell) count, hemoglobin, hematocrit, mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), mean corpuscular volume (MCV), platelet count, red cell distribution width (RDW), and white blood cell differential (including neutrophils, lymphocytes, and monocytes). *There was no documentation that the PT samples were processed for a self-evaluation once the

repaired analyzer was returned to service. *At 10:15 a.m., a request was made for any additional documentation concerning the review of the testing event from the laboratory staff and technical consultant (TC) A. No additional documentation was provided for review. Review on 10/19/23 at 10:10 a.m. of the Medonic hematology analyzer's maintenance records revealed: *The Medonic analyzer was shipped to the manufacturer for repair on 11/2/22. *The analyzer was returned to the laboratory on 11 /28/22. *The laboratory staff had performed verification testing on the repaired analyzer the week of December 5 through 8 of 2022. That testing included the processing of quality control samples and comparison testing of patient specimens with another laboratory. Interview on 10/19/23 at 10:15 a.m. with TC A revealed: *She had been on maternity leave at the time of the missed PT event. *There had been staffing issues during that time period. *The staff members working in the laboratory at the time of the missed PT event were no longer employed at the facility. *All PT reports and documentation were sent to the laboratory director for review. *The laboratory director reviewed all the PT performance reports and corrective actions taken. Review on 10/19/23 of the laboratory's Proficiency Testing policy, revealed: *" If equipment is down or testing is suspended, report this as the 'result' to the Proficiency Testing provider by the due date. Something must be reported for the event" *"Retain all samples, refrigerate or freeze as appropriate." *"Proficiency testing results will be reviewed within 30 days of receipt of results." *"Evaluate all ungraded responses and perform a self-evaluation to verify the accuracy of analytes that are not graded or that are scored 100% due to non-consensus or lack of peer group. Compare your actual performance against the stated target and allowable range of the PT specimens as defined in the participant summary available from the PT provider. Document any corrective action for unacceptable responses as detailed in the steps below." *"The Laboratory Director also must sign the forms as reviewed, and reports are filed in the Proficiency Testing Manual." *"Document all problems in proficiency testing. A Quality Assessment review should be performed and documented to ensure quality patient testing." *"The Laboratory Staff and Director should review all PT scores and corrective action documentation, and sign and date them." Review of the Consultative & Visit Support Summary, dated 12/13/22, revealed: *The report had been completed by laboratory director B. *He had noted under Hematology, "API PT 3rd event submitted as instrument not available. Signed by lab director along with attestation." Review of the Consultative & Visit Support Summary, dated 1/19/23, revealed: *The report had been completed by laboratory director B. *He had noted under Hematology: -"LJ [Levy Jennings] graphs for this December after instrument returned and recalibrated show HCT [hematocrit] and MCV to be low 1-2 SD [standard deviations]. Recal [recalibration] necessary. Done 1-9-23. " -"Medonic mini validation done upon return of the instrument. Few patients compared to Eagle Butte. See separate data." Interview on 10/19/23 at 11:50 a.m. with laboratory director B revealed: *He was aware the analyzer had been sent to the manufacturer for repairs. *He was aware the PT testing event had not been processed. *He could not remember if the laboratory staff had processed the PT samples after the analyzer was returned to the laboratory. *He stated there had been staffing issues during that time. There had been "Times no one was available to run the instrument." *He could not remember reviewing that particular PT survey. *He stated, "It was an oversight on my part for not following up."