Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D2031570	11/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
James Valley Community Health Center	1000 18th St Sw Suite 27, Huron, 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 11/18/21. The James Valley Community Health Center laboratory was found not in compliance with the following requirements: D2006 and D5215.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to process proficiency testing (PT) samples in the same manner as patient specimens for four of eight American Proficiency Institute (API) PT events reviewed (API 2020 Chemistry Core third PT event and 2021 Chemistry Core first, second, and third PT events). Failure to dilute and reanalyze PT samples in the same manner as patient specimens did not ensure the accuracy of patient specimens that were diluted and reanalyzed. Findings include: 1. Review of the API PT event records revealed: *API 2020 Chemistry Core third PT event, human chorionic gonadotropin (HCG) (serum quantitative) HCG-12 and HCG-14 samples were reported as >1,000 mili-international units/milliter (mIU /ml). *API 2021 Chemistry Core first PT event, HCG (serum quantitative) HCG-03 and HCG-04 samples were reported as >1,000 mIU/ml. *API 2021 Chemistry Core second PT event HCG (serum quantitative) HCG-08 sample was reported as >1,000

	mIU/ml. *API 2021 Chemistry Core third PT event, HCG (serum quantitative) HCG-11, HCG-12, HCG-13,and HCG-15 samples were reported as >1,000 mIU/ml. Review of several random patient quantitative HCG quantitative reports revealed patient specimens were routinely diluted and reanalyzed to obtain accurate test results when initial values above the 1,000 mIU/ml analyzer's upper reporting limit were detected. Review of the laboratory's Proficiency Testing policy, signed by the laboratory director, revealed "General Guidelines- Analyze PT specimens according to patient protocols at all times throughout the process." Interview on 11/18/21 at 10:20 a.m. with laboratory personnel A revealed: *She confirmed patient specimens for quantitative HCG testing that resulted in an initial analyzer result of >1,000 mIU/ml were routinely diluted and reanalyzed to provide accurate results above the 1,000 mIU /ml analyzer's upper reporting limit. *She confirmed PT samples were not diluted if an initial analyzer result of >1,000 mIU/ml was reported. The >1,000 mIU/ml result was reported on the PT report without further analysis. *She stated, "A previous technical consultant had told them not to dilute PT specimens."
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 six of six "not graded" American Proficiency Institute (API) PT samples reviewed (API 2021 Chemistry Core first event CH-02, and HCG-04; and API Chemistry Core third event HCG-11, HCG-12, HCG-13, and HCG-15). Findings include: 1. Review of the API PT records for 2021 revealed: *There had been no documentation the following samples had been reviewed for their accuracy. These samples had not been graded due to lack of consensus. *API Chemistry Core first PT event CH-02 sample's alanine transaminase result and HCG-04 sample's human chorionic gonadotropin (HCG) result. *API Chemistry Core third PT event HCG-11, HCG-12, HCG-13, and HCG-15 samples' HCG results. Review of the Proficiency Testing Checklist for both of the above PT events revealed "Were 'not graded' test results evaluated by laboratory to identify potential problems" was marked yes on both checklists. Review of the laboratory's Proficiency Testing policy, signed by the laboratory director, revealed- "Assessment of the Proficiency Testing Report- 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 specimen as defined in the participant summary available from the PT provider. Document any corrective actions for unacceptable responses as detailed in steps below." Interview on 11/18/21 at 9:55 a.m. with the technical consultant confirmed the "not graded" results had not been reviewed.