Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0658956	(X3) Date Survey Completed 10/17/2023
Name of Provider or Supplier Isabel Community Health Center	**Street Address, City, State** 118 North Main, Isabel, 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 10/18/23. Isabel Community Health Center laboratory was found not in compliance with the following requirements: D6054.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on interview and record review, the technical consultant (TC A) failed to ensure one of two laboratory personnel (testing personnel [TP] C) had received an annual competency evaluation for the test methods, they had been performing. Competency assessment ensures the testing personnel are competent to perform test procedures and report test results promptly, accurately, and proficiently. Findings include: 1. Interview on 10/17/23 at 1:15 p.m. with TP B revealed: *The TC visited the clinic twice a year. *The TC would complete the competency assessment during his onsite visit. *TP C only worked Thursdays in the Isabel Community Health Center. The remainder of the week she worked at another health center. Review on 10 /17/23 at 1:20 p.m. of the employee competency assessments for TP C revealed her annual competency assessments had been completed on Tuesday 2/15/22 and on Tuesday 10/3/23. Review on 10/17/23 of the laboratory's Staff Orientation, Training, and Competency policy, effective 12/15/20, revealed: *"As defined by CLIA, the following six(6) procedures are the minimal regulatory requirements for assessment of competency for al personnel performing laboratory testing: 1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. 2. Monitoring the recording and reporting of test results. 3. Review of intermediate test results or worksheets, quality control records,

	proficiency testing results, and preventative maintenance records. 4. Direct observation of performance of instrument maintenance and function checks. 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. 6. Assessment of problem-solving skills." *"The Technical Consultant (TC) for moderate complexity testing is responsible for performing and documenting the competency assessments." Interview on 10/17/23 at 2:25 p.m. via telephone with TC A revealed: *He had been the TC for both Isabel Community Health Center and another health center. *He confirmed he performed the competency assessments during his onsite visits to the clinics. *He was aware TP C only worked Thursdays in the Isabel Community Health Center. *He performed a "dual competency" for TP C as both clinics used the same model hematology analyzer. *He would complete her competency at the other health center. *He would then "use his observations from the other heatlh center for the Isabel competency". *He confirmed he had not observed TP C working in the Isabel Community Health Center. Interview on 10/18/23 at 9:45 a.m. with TP C revealed: *She confirmed she worked at both the Isabel Community Health Center and another health center. *She worked only Thursdays at the Isabel Community Health Center. *The TC had performed her annual competency at the other health center at which she was employed during his onsite visits. *The TC had not been present at the Isabel Community Health Center on the days she worked there.