

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407818	(X3) Date Survey Completed 02/08/2023
Name of Provider or Supplier Mobridge Regional Hospital	Street Address, City, State 1401 10th Ave West, Mobridge, 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 2/8/23. Mobridge Regional Hospital was found not in compliance with the following requirements: D2007, D2009, D2015, D5209, D5449, D6107, and D6120.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to ensure all testing personnel routinely testing patient samples participated in proficiency testing (PT) during 18 of 18 months (8/21 through 1/23) reviewed. Performance of PT verifies laboratory staff were competent to correctly process patient specimens to ensure the accuracy of the patient specimen results reported. Findings include: 1. Review of the American Proficiency Institute PT attestation statements for 2021 and 2022 revealed respiratory therapist D had not performed blood gas PT during that time. Review of the laboratory's Quality Assurance Plan revealed, "Each employee who performs lab testing will complete proficiency testing events according to the P.T. [proficiency testing] schedule and will participate in an annual competency evaluation." Review of the CMS 209 Laboratory Personnel Form revealed respiratory therapist D had been listed as testing personnel. Review of the laboratory's test count form revealed a total of 124 blood gas specimens during 2022. Interview on 2/8/23 at 1:10 p.m. with laboratory supervisor A revealed she confirmed respiratory therapist D processed arterial blood gas specimens and had not participated in PT in the past.</p>
D2009	TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(1)

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure the the attestation statements had been signed by authorized personnel for 10 of 44 proficiency testing (PT) events reviewed (2022 1st, 2nd, and 3rd Immunology /Immunohematology events; 2022 HPS-A and B H. pylori stool antigen events; 2022 COVS-B SARS CoV-2 Serology event; 2022 S-B Diagnostic Immunology event; 2022 Chemistry Miscellaneous 2nd event; 2022 Hematology/Coagulation 3rd event; and 2022 J-C Transfusion Medicine event). The attestation statements confirmed the PT samples had been tested in the same manner as patient specimens. Findings include: 1. Review on 2/8/23 of the 2021 and 2022 completed American Proficiency Institute (API) and College of American Pathologists (CAP) PT events revealed: a. The following testing event attestation statements lacked the laboratory director or the designee's signature on the attestation statement: -2022 API Immunology /Immunohematology 1st testing event -2022 API Immunology/Immunohematology 2nd testing event -2022 API Immunology/Immunohematology 3rd testing event -2022 API Hematology/Coagulation 3rd testing event b. The following testing event attestation statements had been signed by laboratory personnel B, who had not been authorized to sign as the laboratory director's designee: -2022 CAP HPS-A H. pylori stool antigen testing event -2022 CAP HPS-B H. pylori stool antigen testing event -2022 CAP COVS-B SARS CoV-2 Serology testing event -2022 CAP S-B Diagnostic Immunology testing event -2022 API Chemistry Miscellaneous 2nd event c. The following testing event attestation statement had been signed by laboratory supervisor A, who had not been authorized to sign as the laboratory director's designee for the specialty of immunohematology. -2022 CAP J-C Transfusion Medicine testing event d. The following testing event attestation statement had not been signed by the testing personnel who processed the PT samples: *2022 API Immunology /Immunohematology 1st testing event On 2/8/23 at 12:45, a copy of the laboratory's PT policy had been requested from laboratory supervisor A. No policy was provided during the survey. Interview on 2/8/23 at 12:45 p.m. with laboratory supervisor A revealed she confirmed: *The attestation statements had not been signed by the laboratory director or their designee. *Laboratory personnel B had not had written designation from the laboratory director to sign the PT attestation statements as his designee. *She had been designated, in writing, by the laboratory director to sign the attestation statements for all PT events, except for the specialty of immunohematology. *Only the laboratory director was designated to sign the PT event attestation statements for the specialty of immunohematology.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing

samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to maintain a copy of required documentation related to the processing of 9 of 44 proficiency testing (PT) events reviewed (2021 Chemistry Miscellaneous 2nd event; 2021 Microbiology 2nd and 3rd events; 2021 Hematology/Coagulation 3rd event; 2022 Chemistry Miscellaneous 1st event; 2022 Chemistry Core 1st event; 2022 Microbiology 2nd event, 2022 CGL-B 2nd event; and 2022 FH9-B 2nd event). That documentation would ensure the results submitted for evaluation had been the results obtained by the laboratory processing the PT samples. Findings Include: 1. Review on 2/8/23 of the laboratory's 2021 and 2022 American Proficiency Institute (API) and College of American Pathologists (CAP) PT event records revealed: *The laboratory subscribed to PT events through API and CAP. *PT specimens were processed and the results submitted electronically via the company's website upon completion of testing. *The laboratory had the ability to print a copy of the final PT results submitted for evaluation. *The laboratory had not retained copies of final electronically submitted results for evaluation for the following events: -2021 API Chemistry Miscellaneous 2nd testing event -2021 API Hematology/Coagulation 3rd testing event -2021 API Microbiology 3rd testing event -2022 API Chemistry Miscellaneous 1st testing event -2022 API Chemistry Core 1st testing event -2022 CAP FH9-B Hematology Automated Differential Series 2nd testing event *The laboratory had the ability to print a copy of the completed results from the analyzer. *The laboratory had not retained copies of analyzer printouts documenting the results obtained from processing the PT samples for the following events: -2021 API Microbiology 2nd testing event -2022 API Microbiology 2nd testing event -2022 CAP CGL-B Coagulation Limited 2nd testing event On 2/8/23 a copy of the laboratory's PT policy had been requested from laboratory supervisor A. No policy was received during the survey. Interview on 2/8/23 at 12:45 p.m. with laboratory supervisor A revealed she confirmed: *PT results were electronically reported after PT samples had been processed. *The laboratory could print a copy of all final PT results submitted for evaluation. *The laboratory had not printed copies of all final submitted PT results. *The analyzer printouts had not been retained for all PT performed. *Analyzer printouts were routinely shredded after results were entered into the laboratory information system.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on record review and interview the laboratory failed to assess the competency of the technical consultant (C) for 18 of 18 months (8/21 through 1/23) reviewed. Competency assessments ensured the laboratory personnel were competent and had completed the assigned duties. Findings include: 1. Review of the laboratory's CMS

209 Laboratory Personnel Form revealed technical consultant C was listed as a technical consultant for the laboratory. Review of the technical consultant reports revealed that technical consultant C visited the laboratory on the dates of 11/2/21, 5/2/22, 9/8/22 and 11/2/22. Review of the laboratory Quality Assurance Plan revealed that competency assessments were to have been completed yearly on all laboratory personnel. A copy of the laboratories competency assessment policy was requested on 2/8/23 at 12:30 p.m. from laboratory supervisor A. The laboratory staff was unable to provide a copy of the policy. Interview on 2/8/23 at 1:00 p.m. with laboratory supervisor A revealed: *She confirmed a competency assessment for technical consultant C was not completed in 2021 or 2022. *She was unaware that competency assessments were required for the technical consultant.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review, and interview, the laboratory failed to perform a positive and negative control to verify the accuracy of specimen test results for 11 of 31 days reviewed (1/7/23, 1/8/23, 1/9/23, 1/11/23, 1/12/23, 1/13/23, 1/21/21, 1/22/23, 1/24/23, 1/28/23, and 1/29/23). Performance of quality control (QC) ensures the accuracy of patient specimen results reported. Findings include: 1. Review of the laboratory's records revealed: *The laboratory had begun testing of patient SARS CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) panel specimens using the Cepheid GeneXpert analyzer on 4/7/21. *External positive and negative QC samples had been processed monthly and with each change of lot number or new shipment. *The laboratory did not have an individual quality control plan (IQCP) in effect which would have allowed the laboratory to process QC at the minimum number and frequency required by the manufacturer. Review of the laboratory's January 2023 Cepheid GeneXpert analyzer records revealed: *QC samples had been processed on 1/3/23. *QC results had not been documented on the 11 dates listed above. *Patient specimen testing had been reported to the provider on these days without QC having been performed to ensure the accuracy of the test results. Review of the laboratory's annual test volume form revealed the laboratory had reported a total of 286 patient specimen SARS CoV-2, Influenza A, Influenza B, and RSV panel results in 2022. Interview with technical supervisor A on 2/8/23 at 12:45 p.m. revealed she confirmed: *QC had not been performed on the dates listed above. *The laboratory had performed QC monthly and with each new lot or shipment. *The laboratory had not had an established IQCP signed by the laboratory director.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether

supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory director failed to specify in writing the duties delegated to one of one laboratory personnel (B), including the duty of signing proficiency testing (PT) attestation statements as the designee. Findings Include: 1. Review of the 2022 American Proficiency Institute (API) and the College of American Pathologists (CAP) PT testing event signed attestation statements revealed the following attestation forms had been signed by laboratory personnel B: *2022 CAP HPS-A H. pylori stool antigen testing event *2022 CAP HPS-B H. pylori stool antigen testing event *2022 CAP COVS-B SARS CoV-2 Serology testing event *2022 CAP S-B Diagnostic Immunology testing event On 2/8/23 the surveyor requested a copy from laboratory supervisor A of the laboratory director's designation of duties for laboratory personnel B that would have authorized her to sign the PT attestation forms as the laboratory director's designee. No documentation was provided during the survey. Interview on 2/8/23 at 12:45 p.m. with laboratory supervisor A revealed she confirmed the laboratory did not have a written delegation of duties signed by the laboratory director that designated laboratory personnel B to sign the attestation statements as the designee. The laboratory director was unavailable for interview at the time of the survey.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and interview, laboratory supervisor A failed to ensure that one of six laboratory personnel (respiratory therapist D) had received a competency evaluation in 2022 for the test methods they had performed under the laboratory's certificate. Competency assessment verifies testing personnel were competent to correctly process patient specimens and to ensure the accuracy of the patient specimen results reported. Findings include: 1. Review on 2/8/23 at 12:50 p.m. of the employee competency records revealed: *Respiratory therapist D did not have a competency evaluation documented in 2022. *A request was made to laboratory supervisor A for any additional documentation of the competency assessments. *No additional documentation was provided during the survey. Review of the CMS 209 Laboratory Personnel Form revealed respiratory therapist D had been listed as testing personnel. Review of the laboratories Quality Assurance Plan revealed, "IV. Personnel Competency ... Indicators: Each laboratory employee who performs lab testing will complete proficiency testing events according to the P.T. [proficiency testing] schedule and will participate in an annual competency evaluation. Monitor: The laboratory supervisor will review the results of the P.T for each employee and will conduct annual competency evaluations in the first quarter of the new year." Review

of the laboratory's annual testing count form revealed the laboratory had reported a total of 124 blood gas patient specimens in 2022. Interview on 2/8/23 at 1:00 p.m. with technical supervisor A revealed she confirmed: *Respiratory therapist D had performed arterial blood gas testing in 2022. *She was aware a yearly competency had been required but had not completed one in 2022.