

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0041551	(X3) Date Survey Completed 09/24/2019
Name of Provider or Supplier Milbank Area Hospital/Avera Health	Street Address, City, State 301 Flynn Drive, Milbank, 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 9/24/19. The Milbank Area Hospital/Avera Health laboratory was found not in compliance with the following requirements: D5407, D5471, D5555, D5775, and D6120.
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on the review of laboratory procedure manuals and interview with the laboratory manager, the laboratory failed to ensure seven of ten procedure manuals were approved, signed, and dated by the new laboratory director prior to use. Findings include: 1. Observation on the morning of 9/24/19 revealed the following manuals had not been approved, signed, and dated by the new laboratory director before use: *Blood Bank Policies Manual (that manual contained numerous revised but unapproved policies). *Bio Merieux Vitek Compact 2 Manual. *Laboratory Policies Manual. *Laboratory Specimen Collection Manual. *Meditech C/S manual. *Laboratory Safety Manual. *Bacteriology Procedures Manual. An interview on 9/24/19 at 3:40 p.m. with the laboratory manager revealed: *He confirmed the listed manuals and revised policies had not been approved, signed, and dated, to date. *He became laboratory director on 7/1/19. *He had made an initial visit to the laboratory on 9/9/19. *He had signed several manuals at that time.</p>
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i)</p>

Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation of the potassium hydroxide (KOH) reagent, review of the annual test volume form, and interview with the laboratory manager and staff A, the laboratory failed to verify each lot number or shipment of the KOH reagent for its positive reactivity to ensure accurate results prior to testing patient specimens for twenty-one of twenty-one months (1/1/18 - 9/24/19). Findings include: 1. Observation on 9/24/19 at 12:50 p.m. revealed a bottle of KOH reagent (lot 4810K78, expiration date 9/21) was available for use on patient specimens. The bottle of KOH reagent was approximately three-quarters full. There was no documentation whether or not the missing reagent had been used on patient specimens or discarded. Review of available records revealed KOH quality control (QC) had not been documented in 2018 or to date in 2019 for any lot number or different shipments of the same lot number. Review of the annual testing volume survey form indicated twenty-seven KOH patient tests had been performed during 2018 without reagent QC to ensure accurate patient test results. Interview on 9/24/19 at the above time with the laboratory manager revealed he was unaware QC was required of a new lot number or shipment before use on patient samples. Interview with laboratory staff A on 9/24/19 at 3:45 p. m. revealed they had not done QC on the KOH reagent as long as she had worked there. She had worked there almost twenty years.

D5555

IMMUNOHEMATOLOGY

CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on observation, alarm check documentation review, quality assurance (QA) reports, blood bank refrigerator and freezer continuous temperature monitoring chart review, transfusion record review, policy and procedure reviews, and interview with the laboratory manager, the laboratory failed to: *Ensure the blood bank alarm system sounded at the appropriate temperature to ensure a prompt response when the internal blood storage refrigerator temperature was maintained within the correct range for six of seven quarterly alarm tests (4/22/18, 7/19/18, 10/18/18, 2/4/19, 5/16/19, and 8/25/19). *Ensure the blood bank alarm sounded at the nurses station at the same time the alarm sounded in the laboratory. Findings include: 1. Observation on 9/24/19 at 1:00 p. m. of quarterly Blood Bank Thermometer - Alarm Check Report forms revealed: a. 4/22/18: *Blood bank refrigerator low alarm activation temperature was -3.7 C. *Blood bank refrigerator high alarm activation temperature was 11.9 C. *Blood bank freezer high alarm activation temperature was -8.6 C. b. 7/9/18: *Blood bank refrigerator low

alarm activation temperature was -2.9 C. *Blood bank refrigerator high alarm activation temperature was 12.0 C. *Blood bank freezer high alarm activation temperature was -10.8 C. c. 10/18/18: *Blood bank refrigerator low alarm activation temperature was -2.1 C. *Blood bank freezer high alarm activation temperature was -16.1 C. d. 2/4/19: *Blood bank refrigerator low alarm activation temperature was -2.4 C. *Blood bank refrigerator high alarm activation temperature was 7.9 C. e. 5/16/19: *Blood bank refrigerator low alarm activation temperature was -2.9 C. *Blood bank freezer high alarm activation temperature was -13.9 C. f. 8/25/19 *Blood bank refrigerator low alarm activation temperature was -3.9 C. *Blood bank freezer high alarm activation temperature was -13.6 C. g. Laboratory staff B performed the above alarm activation check reports. *She had documented all the above blood bank activation alarm checks as acceptable. h. The laboratory manager signed the above alarm activation check reports. i. There was no documentation of corrective actions taken on any of the above alarm check reports. Review of the 2018 yearly QA report indicated all quarterly blood bank alarm checks were acceptable. Review of the blood bank refrigerator and freezer continuous temperature recording charts from 1/22/18 (date of last successful alarm check) to present revealed no temperature anomalies. There was no documentation on the refrigerator or freezer charts of the blood bank alarm activation checks. Review of the laboratory's transfusion records revealed: *Fifty-nine units of leukoreduced packed red blood cells (LRBC) and four units of fresh frozen plasma (FFP) had been transfused to date in 2019. *Seventy-eight unit of LRBCs and 6 units of FFP had been transfused from 1/22/18 to 12/31/18. Review of the undated Procedure for Blood Bank Monitoring- Alarm Checks revealed: *"The blood bank refrigerator and the blood bank freezer are equipped with audible alarms in the Laboratory." *"In addition, the blood bank refrigerator has a remote alarm at the nurse's station, which is staffed 24 hours a day." *"Audible alarm function is checked quarterly each year to verify Alarm function should equipment fail to maintain specified temperature ranges." *"The acceptable temperature range for the blood bank refrigerator is 1-6 C." *"In the event the alarm should sound ('Red' light on) the following steps should be taken IMMEDIATELY: ... Notify laboratory staff that the remote alarm has sounded. If the alarm sounds after laboratory hours, nursing staff would call the tech on-call for further instructions." Review of the undated Procedure for Blood Bank Refrigerator Alarm Check revealed: *"The starting point temperature should be between 1-6 C." *"Immerse an easy to read calibrated thermometer in the container with the alarm thermocouple." *"For Low activation: Alarm should sound at 1.5 C." *"Place the container with the thermocouple in a pan containing an ice and water slush at a temperature of -4 C or colder." *"Keep the container in the pan of cold slush, and gently agitate it periodically until the alarm sounds." *"Record this temperature as the low-activation temperature. Should be lower than 1 C." *"For High Activation: Alarm should sound at 5.5 C." *"Place the container with the thermocouple and thermometer in a pan containing cool water [12-15 C]." *"Record the temperature at which the alarm sounds as the high-activation temperature which should be greater than 6 C." *"If temperatures of alarm activation are too low or too high take appropriate corrective action as specified by the manufacturer, record the nature of the corrections, and repeat the alarm check to document that the corrective actions were done." * "Notes: All remote alarms should sound at the same time as the lab's alarm sound is activated." Review of the undated Procedure for Blood Bank Freezer Alarm Check revealed: *Use a thermometer or thermocouple, independent from that built into the system that will accurately indicate the temperature of alarm activation. Compare these temperatures registered on the recorder." *"Alarm should sound at -20 C." *"If the alarm sounds at too high a temperature, take appropriate corrective action as specified by the manufacturer, record the nature of the corrective actions, and repeat the alarm check to document that the corrective actions were

done." * "Notes: All remote alarms should sound at the same time as the lab's alarm sound is activated." 2. Interview with the laboratory manager on 9/24/19 at 1:00 p.m. revealed: *There was a five minute delay between the alarm sounding in the laboratory and the alarm sounding at the nurses station. *He could not recall how long the delay had been in effect. *The delay had been instituted, so the nurses would not be bothered by the alarm sounding when the door had been inadvertently left open. *He agreed the blood bank alarms should sound in the laboratory and at the nurses station at the same time. *He confirmed the alarm activation temperatures were unacceptable. *He "must not have noticed" the unacceptable temperatures when he reviewed and signed the alarm check reports as acceptable. *He confirmed the alarm activation temperature checks were not visible on the refrigerator and freezer continuous temperature recording charts. *He agreed the alarm activation temperature checks should have produced a visible temperature spike on the charts. *He believed the unacceptable temperatures were due to the technician waiting for nursing to call and report the alarm. *He believed the laboratory staff member had failed to follow the appropriate procedure. Laboratory staff B was unavailable to interview at the time of the survey.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on quality assessment (QA) activities review and interview with the laboratory manager, the laboratory failed to monitor the differences between 7 of 11 analytes (sodium, potassium, chloride, creatinine, glucose, blood urea nitrogen, and carbon dioxide) performed by multiple instruments (Abbott i-STAT versus Beckman AU 480). Those methods or instruments had not been evaluated twice a year in 2018 or to date in 2019 to determine if their differences had been acceptable. Findings include: 1. Review of the laboratory's 2018 and 2019 QA reports revealed comparison testing had not been completed twice a year for sodium, potassium, chloride, creatinine, glucose, blood urea nitrogen and carbon dioxide between the Abbott i-STAT and the Beckman AU 480. Interview on 9/24/19 at 1:00 p.m. with the laboratory manager revealed: *The laboratory used the Abbott i-STAT as a back-up analyzer for the Beckman AU 480. *He was not aware comparison testing between the two analyzers was required. He agreed it was a good idea and probably should be done.

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 review of Blood Bank Thermometer- Alarm Check Reports and interview with the laboratory director, the laboratory failed to ensure one of one laboratory staff member (staff B) had been trained to properly perform the blood bank alarm check procedure. Findings include: 1. Review of the quarterly Blood Bank Thermometer- Alarm Check Reports revealed: *The following reports had unacceptable alarm activation temperatures documented for the blood bank refrigerator and freezer: 4/22/18, 7/9/18, 10/18/18, 2/4/19, 5/16/19, and 8/25/19. *Laboratory staff B had performed and documented the alarm activation checks. *Those reports were all marked acceptable. *There was no corrective action documented for the unacceptable alarm activation temperatures. Interview with the laboratory manager on 9/24/19 at 1:00 p.m. revealed: *He confirmed laboratory staff B had performed the alarm activation checks. *He confirmed the reports had unacceptable alarm activation temperatures documented for both the blood bank refrigerator and freezer. *He confirmed there was no corrective actions documented for the unacceptable alarm activation temperatures. *He believed laboratory staff B had failed to follow the laboratory's procedures for monitoring and performance of the blood bank alarm temperature activation checks for the blood bank refrigerator and freezer. *He agreed additional training might be needed. Refer to D5555.