

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  43D0658923	<b>(X3) Date Survey Completed</b>  08/15/2018
<b>Name of Provider or Supplier</b>  Avera St Benedict Health Center	<b>Street Address, City, State</b>  401 West Glynn Drive, Parkston, SD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 8/15/18. The Avera St Benedict Health Center laboratory was found not in compliance with the following requirements: D5471 and D5477.
<b>D5471</b>	<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) 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Individualized Quality Control Plan (IQCP) for streamlined quality control (QC) of commercial identification (ID) cards for the Vitek 2 and interview with the laboratory supervisor, the laboratory failed to check each lot number or shipment of five of five lot numbers reviewed of Vitek 2 gram positive and negative ID cards (lot # 241397440, 2410257403, 2410473203, 2420024123, and 2420535403) for their positive and negative reactivity prior to use for patient testing to ensure accurate identification of microorganisms. Findings include: 1. Review of the bacteriology QC records for three lot numbers of Vitek 2 gram negative ID cards (241397440, 2410267403 and 2410473203, tested 1/25/17, 9/13/17, and 6/18/18, respectively) revealed: *The cards did not have the positive reactivity checked in the L-pyrrolydonyl-arylamidase, L-arabitol, hydrogen sulfide production, glutamyl arylamidase pNA, beta-alanine arylamidase pNA, urease, D-Tagatose, 5-keto-D-gluconate, alpha-gluconidase, lysine decarboxylase, L-histidine assimilation,</p>

coumarate, beta-glucuronidase, l-malate assimilation, ellman, and L-lactate assimilation biochemical wells. \*The cards did not have the negative reactivity verified in the gamma-glutamyl-transferase biochemical well. \*Gram negative ID card lot 2410473203 was currently in use for patient testing at the time of survey. 2. Review of the bacteriology QC records for two lot numbers of Vitek 2 gram positive ID cards (2420024123 and 242066503, tested 10/5/16 and 1/17/18, respectively) revealed: \*The cards did not have the positive reactivity verified in the alpha-glucosidase, Ala-Phe-Pro arylamidase, cyclodextrin, L-aspartate arylamidase, leucine arylamidase, beta-glucuronidase, alanine arylamidase, D-sorbitol, and arginine dihydrolase 2 biochemical wells. \*The cards did not have the negative reactivity verified in the arginine dihydrolase 1, beta-galactosidase, D-galactose, D-maltose, bacitracin resistance, novobiocin resistance, growth in 6.5% sodium chloride, D-mannitol, and D-trehalose biochemical wells. \*Gram positive ID card lot 2420535403 was currently in use for patient testing. Review of the Vitek 2 ID IQCP policy, approved and signed by the laboratory director on 11/8/15, revealed the IQCP did not address the identity and number of QC organisms to be tested. Review of the annual testing volume survey form indicated 463 patient microorganism IDs had been performed on those lot numbers of cards in 2017. Interview on 8/15/18 at 10:10 a.m. with the laboratory supervisor revealed she thought the IQCP plan covered QC. She stated they were following Clinical Laboratory Standards Institute (CLSI) standards for streamlined QC. She was unaware that Clinical Laboratory Improvement Amendments of 1988 no longer accepted CLSI standards as of January 2015.

**D5477**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on quality control (QC) record review, Individualized Quality Control Plan (IQCP) for commercially prepared Clinical Laboratory Standards Institute (CLSI)-Exempt Media policy, and interview with the laboratory supervisor, the laboratory failed to ensure QC had been performed on six of six different types of media (trypticase soy agar with 5% sheep blood agar, MacConkey II agar, chocolate agar, BacT/Alert SN blood culture bottles, BacT/Alert SA blood culture bottles, and BacT /Alert PF Plus blood culture bottles) for accurate and reliable performance prior to being used with patient culture specimens. Findings include: 1. Review of the Quality Control Log for Remel Media revealed no documentation of 27 lot numbers of the above identified media from 11/1/17 through 6/19/18 for the ability to support growth, the ability to select, or inhibit specific organisms, or produce a biochemical response as applicable for each type of media. The lot numbers reviewed were: \*Trypticase soy agar with 5% sheep blood agar: 225334, 247681, 257728, 275159, 257864, 292395, 297390, 313825, 316520, 332624, and 352573. \*MacConkey II agar: 229472, 245682, 275237, 251082, 293681, 322626, and 339263. \*Chocolate agar: 225016, 294457, 265802, 295739, 323507, and 341166. \*BacT/Alert SN blood culture bottle: 1050474. \*BacT/Alert SA blood culture bottle: 1050578. \*BacT/Alert PF Plus blood

culture bottle: 4050298. Review of the IQCP for Commercially Prepared CLSI-Exempt media policy, approved and signed by the laboratory director on 11/18/15 revealed: \*An IQCP had been developed. \*The quality control plan of the IQCP did not address the ability to support sterility, growth, select or inhibit specific organisms, or produce a biochemical response as applicable for each type of media. Interview on 8/15/18 at 10:10 a.m. with the laboratory supervisor revealed she thought their IQCP plan covered QC requirements. She stated they were following CLSI standards. She was unaware that Clinical Laboratory Improvement Amendments of 1988 no longer accepted CLSI standards as of January 2015. She was unaware that revision required documentation of physical characteristics of media, sterility, and ability to support growth of microorganisms upon receipt of a new lot number or shipment was required in-house on all media.