

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0519862	(X3) Date Survey Completed 08/02/2018
Name of Provider or Supplier So Big Horn Co Hospital	Street Address, City, State 388 Us Hwy 20 South, Basin, WY	
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
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 bacteriology procedure manual review, lack of documentation, and interview with staff, the current laboratory bacteriology procedure manual lacked documentation the current director signed and dated the manual as approved. Findings include: 1. The bacteriology procedure manual including Gram's stain, urine, blood, and sputum cultures, and susceptibility testing failed to include the current director's signature and date of approval. 2. In an interview with staff on 08/02/2018 at approximately 5:00 P.M., staff stated the director had most likely not been given the bacteriology procedure manual to sign along with the other procedures resulting in the lack of signature and date of approval. Based on instrument manufacturer's operators manual review, lack of documentation, and confirmation by staff, the director failed to sign and date the Pentra 400 chemistry analyzer as the approved laboratory testing method for routine chemistry testing for 20 tests reported. The laboratory performed approximately 1500 tests per year using the Pentra 400. Findings include: 1. The operator's manual review cover page included the statement, "This manual has been accepted as the procedure manual for this instrument." The signature of the technical supervisor followed with the date of 04/25/2017. 2. In an interview conducted on 08/02/2018 at approximately 3:30 P.M., the technical supervisor confirmed the Pentra 400 instrument operator's manual had not been signed and dated as approved by the current laboratory director.</p>
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</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.

This STANDARD is not met as evidenced by:

Based on quality control record review, lack of documentation and interview with staff, the laboratory failed to check each new lot number of blood culture media for the ability to support growth for 2 of 2 years of testing reviewed, (August 2016 to August 2018). The laboratory performed approximately 100 blood cultures per year. Findings include: 1. Quality control records reviewed failed to include documentation the media was checked for it's ability to support bacterial aerobic and anaerobic growth for each shipment or lot number of media received from August 2016 to August 2018. 2. In an interview conducted on 08/02/2018 at approximately 3:00 P.M., staff stated the laboratory did not verify the blood culture media's ability to support bacterial growth for the past 2 years or develop an Individualized Quality Control Plan.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on bacteriology test records review, lack of documentation and interview with staff, the laboratory failed to document the primary isolation media used for 4 of 5 patient culture sources (urine, sputum, throat, and wound), and the resulting colonial growth description or lack of growth for each media type used for specimen culture for two years of culture records reviewed. The laboratory performed approximately 150 cultures per year. Findings include: 1. The laboratory test records failed to include the culture test results for each media type used to culture for the presence or absence of bacterial growth and the description of the colonies present for urine, sputum, throat and wound cultures. 2. In an interview with staff on 08/02/2018 at approximately 4:00 P.M., staff stated they did not record growth or no growth and description of colonial morphology for each type of media inoculated.