

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0662176	(X3) Date Survey Completed 08/21/2018
Name of Provider or Supplier Memorial Hospital Of Carbon County	Street Address, City, State 2221 W Elm St, Rawlins, 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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing records review and interview with the laboratory supervisor, the laboratory failed to include a review of the effectiveness of corrective actions taken to resolve proficiency testing individual analyte failures for wound cultures, acetaminophen, gentamicin, and Troponin tests. Findings include: 1. Proficiency testing records review included corrective actions taken each time the laboratory failed to receive scores of 100%. The laboratory corrective actions included retesting the proficiency sample (if specimens were available), recording the retested results and crediting the error to recalibration or random error for laboratory. 2. In an interview with the supervisor on 08/21/2018 at approximately 12:45 P.M., the laboratory supervisor confirmed the laboratory failed to identify the root cause for repeated proficiency testing failures. In the interview the manager confirmed the laboratory had not taken measures to educate staff on proficiency testing specimen handling and mixing.</p>
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>

This STANDARD is not met as evidenced by:
Based on procedure manuals review and confirmation by the laboratory supervisor, the current director failed to sign, and date as approved the laboratory procedure manuals for Bacteriology, Mycobacteriology, Mycology, Virology, Immunology, Chemistry, Hematology, and Immunochemistry testing. Findings include: 1. The laboratory directorship changed in 2017 to the current director. 2. Procedure manuals review failed to include the current director's signature as approval. 3. In an interview conducted on 08/21/2018 at approximately 1:30 P.M., the laboratory supervisor confirmed the current director had not approved the laboratory's procedures since assuming the position of laboratory director.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(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--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on direct observation, lack of documentation, and interview with staff, the laboratory failed to document they performed two levels of quality control each day of testing using the Alere Triage instrument. The laboratory performed testing on the Alere Triage instrument when the primary instrument was inoperable. Findings include: 1. Testing observed on 08/21/2018 at approximately 10:45 A.M., using the Alere Triage instrument for Troponin I testing failed to include using two levels of quality control prior to reporting patient results on 08/21/2018. 2. In an interview with the laboratory supervisor on 08/21/2018 at approximately 1:00 P.M., the laboratory supervisor stated the Alere Triage instrument did not have an Individualized Quality Control Plan (IQCP) and the laboratory did not perform two levels of quality control each day of testing.

D5471

CONTROL PROCEDURES
CFR(s): 493.1256(e)(1)(g)

(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 microbiology media quality control records review, lack of documentation and interview with staff, the laboratory failed to check each lot number or shipment of

MacConkey, Sheep's Blood Agar, Methicillin Resistant Staphylococcus aureas agar, Streptococcus A Selective Agar, and Fungal Culture media for sterility, ability to support growth, and if indicated inhibition for 6 of 10 media types reviewed for testing performed from August 2016 to August 2018. The laboratory performed approximately 1300 cultures annually. Findings include: 1. The laboratory media control records failed to include documentation the laboratory checked MacConkey, Sheep's Blood Agar, Methicillin Resistant Staphylococcus aureas agar, Streptococcus A Selective Agar, and Fungal Culture agar with each shipment or new lot number received. 2. In an interview with microbiology staff on 08/21/2018 at approximately 1:45 P.M., staff confirmed they did not check each of the primary isolation media types for sterility, ability to support growth and if indicated, inhibition of growth.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with staff, the laboratory failed to ensure Wright's stain was checked each day of testing for 2 of 2 years of testing reviewed, (August 2016 to August 2018). The laboratory performed approximately 2 manual white blood cell differentials each day of testing. Findings include: 1. The laboratory lacked documentation they evaluated Wright's stain each day of testing to ensure the stain provided predictable staining characteristics. 2. In an interview conducted on 08/20/2018 at approximately 4:45 P.M., staff confirmed they did not record Wright's stain quality assessment each day of testing.