

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0409807	(X3) Date Survey Completed 07/24/2018
Name of Provider or Supplier Sheridan Memorial Hospital Association	Street Address, City, State 440 West Laurel Avenue, Plentywood, MT	
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	Based on an on-site recertification survey conducted on 7/24/18, deficiencies were cited for Sheridan Memorial Hospital in Plentywood, MT.
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to follow manufacturer instructions for establishing a mean of the patient (PT) normal range with each new lot of RecombiPlasTin 2G reagent from 7/19/16 to 7/24/18. The findings include: 1. On 7/24/18 at 7:45 a.m., an Instrumentation Laboratory ACL Elite coagulation analyzer was observed in the laboratory. 2. On 7/24/18 at 11:00 a.m., a mean of the PT normal range of 11.3 seconds was observed on the analyzer. 3. On 7/24/18 at 11:00, staff member A stated the mean was not done for this lot and the data for the previous lot had been discarded. 4. A review on 7/24/18 at 11:00 a.m. of the manufacturer instructions for RecombiPlasTin 2G reagent for the ACL Elite analyzer included instructions to enter "the ISI value from the insert and establish the mean of the PT normal range with each new lot."</p>
D5425	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3)</p> <p>The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to document and retain in-house data established by the laboratory for one of one Individualized Quality Control Plan (IQCP) from 7/19/16 through 7/24/18. The findings include: 1. A review at 4:15 p.m. of the BioRad Tox/See Drug Screen Test IQCP lacked documentation of in-house data to support the number and frequency of controls in the quality control plan (QCP). 2. On 7/24/18 at 4:15 p.m., staff member A stated the data was not with the IQCP.

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 record review, and interview, the laboratory failed to perform positive and negative reactivity with each lot of negative identification (ID) panels for 2 of 35 biochemical reactions on the panel, for one of one lot of panels reviewed. The findings include: 1. A review on 7/24/18 at 2:30 p.m. of the Microscan Negative ID Panel Type 2 Biochemical Quality Control Report Form included two biochemical reactions without both positive and negative reactivity for lot number 5/12/18. a. The biochemical reaction TO>4 indicating Tobramycin resistance lacked a positive reactivity. b. The biochemical reaction P>4 indicating Penicillin resistance lacked a negative reactivity. 2. On 7/24/18 at 2:30 p.m., staff member A stated more organisms were not performed.

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 observation, record review, and interview, the laboratory failed to document growth, inhibition of growth, and biochemical response for three of four medias from 7/19/16 to 7/24/18. The findings include: 1. On 7/24/18 at 2:15 p.m., media was observed in the laboratory refrigerator, including chocolate agar, eosin methylene blue (EMB) agar, blood agar, and strep selective agar. 2. A review on 7/24/18 at 2:15 p.m.

of the packing slips lacked required documentation for three medias. a. Blood agar lacked documentation of growth. b. EMB agar lacked documentation of growth and inhibition of growth. c. Strep selective agar lacked documentation of appropriate biochemical responses. 3. On 7/24/18 at 2:15 p.m., staff member A stated organisms are grown on the blood, EMB, and strep selective agar as stock cultures but are not currently documented.

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 record review and interview, the laboratory failed to perform regular inspections of the blood bank temperature alarm system from 7/19/16 to 7/24/18. The findings include: 1. A review on 7/24/18 at 3:00 p.m. of the Blood Bank Temperature and Alarm Check form included alarm checks performed on 12/13/16, 7/19/17, and not again until 6/8/18. 2. A review on 7/24/18 at 3:00 p.m. of the Blood Bank Temperature and Alarm Check form included handwritten instructions to perform the alarm checks semi-annually instead of the quarterly checks as originally printed on the form. 3. On 7/24/18 at 3:00 p.m., staff member A stated the alarm checks were missed.