

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0662194	(X3) Date Survey Completed 04/10/2019
Name of Provider or Supplier Memorial Hospital Of Converse County	Street Address, City, State 111 South 5th Street, Douglas, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, direct observation, procedure manual review, and interview with the laboratory supervisor, the laboratory failed to record the cryostat temperature for 1 day of frozen section testing performed on 12/27/2018 for two cases of frozen section testing for a total of 9 specimens processed. Findings include: 1. The laboratory failed to record the temperature of the cryostat documenting the instrument was operating at the selected temperature for the type of specimen being processed on 12/27/2018. 2. The Cryostat was observed to be operating at -31 degrees C on 04/10/2019. The range of acceptable temperature stated in the laboratory procedure was -19 to -23 degrees C. 3. In an interview conducted 04/10/2019 at approximately 8:15 A. M., the laboratory supervisor confirmed the laboratory did not record the cryostat temperature each day of testing for one day testing was performed since opening.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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</p>

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 patient test reports review, lack of documentation, and interview with the laboratory supervisor, the laboratory failed to check Hematoxylin and Eosin (H&E) stain each day of testing for intended reactivity and predictable staining characteristics for 1 of 1 testing day (December 27, 2018). Findings include: 1. Patient test reports reviewed include histopathology diagnoses read from H&E stained slides for histopathology cases 11846892 and 11847573. 2. In an interview conducted on 04/10/2019 at approximately 8:35 A.M. the laboratory supervisor confirmed the laboratory did not record stain adequacy on 12/27/2018, the only day frozen section staining was performed.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
No deficiency details available.