

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2161638	(X3) Date Survey Completed 09/30/2021
Name of Provider or Supplier Memorial Hospital Of Converse County Medical	Street Address, City, State 700 Center 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on new instrumentation and new test method verification study review, lack of documentation, and staff interview, the laboratory failed to verify precision for 1 of 1 new testing methodologies (Medtox urine drug screens). The laboratory performed approximately 300 urine drug screens per year. The findings were: 1. Review of the 12 /18/19 new instrument and test method verification study for the Medtox urine drug screen test system showed the performance specification of precision had not been verified prior to testing patient samples. 2. Interview with the laboratory manager on 9 /30/21 at 9:20 AM confirmed the laboratory had not completed the verification studies to include precision prior to testing patient samples.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p>

This STANDARD is not met as evidenced by:
Based on review of personnel competency assessments, review of policy and procedure, and staff interview, the technical consultant failed to ensure 2 of 2 testing personnel (TP #1, TP #2) were evaluated semiannually for competency during the first year of patient testing. The laboratory performed approximately 300 urine drug screens per year. The findings were: 1. Review of the initial competency assessment for TP #1 and TP #2 showed training and education was provided on 1/7/20 for performing urine drug screens on the Medtox test system. There was no documentation to show a semiannual competency assessment had been completed. 2. Interview with the technical consultant on 9/30/21 at 9 AM confirmed the semiannual competency assessments had not been completed. 3. Review of the policy and procedure titled "Competency Monitoring of Laboratory Personnel", last revised 6 /2016, showed "Laboratory employees will be evaluated after initial training, semi-annually during the first year for new employees, and annually there after."

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of personnel competency assessments, review of policy and procedure, and staff interview, the technical consultant failed to ensure 2 of 2 testing personnel (TP #1, TP #2) had an annual competency assessment after the first year of patient testing. The laboratory performed approximately 300 urine drug screens per year. The findings were: 1. Review of the initial competency assessment for TP #1 and TP #2 showed training and education was provided on 1/7/20 for performing urine drug screens on the Medtox test system. There was no documentation to show an annual competency assessment had been completed after the first year of patient testing. 2. Interview with the technical consultant on 9/30/21 at 9 AM confirmed the annual competency assessments had not been completed. 3. Review of the policy and procedure titled "Competency Monitoring of Laboratory Personnel", last revised 6 /2016, showed "Laboratory employees will be evaluated after initial training, semi-annually during the first year for new employees, and annually there after...After the employee has performed his/her duties for approximately one year, competency will be assessed annually."