

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D1007866	(X3) Date Survey Completed 10/01/2021
Name of Provider or Supplier Oregon Trail Rural Health Clinic	Street Address, City, State 525 East Birch Street, Glenrock, 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 test methodologies (Medtox urine drug screens). The laboratory performed approximately 5 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 10/1/21 at 9 AM confirmed the laboratory had not completed the verification studies to include precision prior to testing patient samples.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records, review of policy and procedure, and staff interview, the technical consultant (TC) failed to ensure 1 of 1 testing personnel (TP #1) was evaluated for competency prior to testing patient samples or anytime thereafter. The laboratory performed approximately 5 urine drug screens per year. The findings were: 1. Review of the laboratory's records showed no evidence an initial, semiannual, or annual competency assessment had been completed for TP #1. 2. Interview with the TC on 10/1/21 at 8:55 AM revealed TP #1 had started testing patient samples in January 2020 and had been trained, however the documentation could not be located. In addition, the TC confirmed the semiannual and annual competency assessments had not been completed.