

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408585	(X3) Date Survey Completed 03/19/2024
Name of Provider or Supplier Langdon Prairie Health	Street Address, City, State 909 2nd St, Langdon, ND	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to twice annually verify the accuracy of 1 of 2 non-regulated analytes (troponin) on the iSTAT analyzer in 2023. The laboratory performed one troponin patient test on the iSTAT analyzer in 2023. Findings include: 1. Reviewed at 08:15 a.m. on 03/19/24, the 2023 proficiency testing records indicated the laboratory did not participate in proficiency testing for iSTAT troponin. 2. Upon request, the laboratory failed to provide evidence of a second accuracy verification in 2023 for iSTAT troponin. 3. Reviewed at 1:50 p.m. on 03/19/24, the 2023 iSTAT patient records showed one patient troponin test performed on 07/02/23. 4. During interview at 10:15 a.m. on 03/19/24, the laboratory supervisor (#1) confirmed the laboratory performed patient testing for iSTAT troponin in 2023 and did not verify the accuracy of this test a second time in 2023. 5. Reviewed on 03/19/24 the policy "Proficiency Testing," dated 01/28/15, stated, ". . . The lab must perform PT [proficiency testing] at least three times per year on each analyte. . . ."</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on record review, procedure review, and staff interview, the laboratory failed to perform a positive and negative control each day of patient testing for urine drug screens on the MEDTOX Scan analyzer for 5 of 5 patient testing days (February 1, 2, 7, 21, and 29) in February 2024. The laboratory performed six urine drug screen patient tests on days with no quality control (QC) performance in February 2024. Findings include: 1. Reviewed on 03/19/24, the patient testing records for urine drug screens on the MEDTOX Scan analyzer indicated performance of patient testing on the following days in February 2024: February 1, 2, 7, 21, and 29. 2. Reviewed on 03/19/24, the February 2024 QC records for urine drug screens on the MEDTOX Scan analyzer indicated the performance of positive and negative controls on February 3, 10, 17, and 24. Upon request on 03/19/24, the laboratory failed to provide evidence of QC performance on February 1, 2, 7, 21, and 29. 4. During interview at 3:10 p.m. on 03/19/24, the laboratory supervisor (#1) confirmed the laboratory performed QC weekly and had failed to perform QC each day of patient testing for urine drug screens on the MEDTOX Scan analyzer. 3. Reviewed on 03/19/24, the procedure "MEDTOX URINE DRUG SCREEN," effective August 2021, stated, ". . . MEDTOX External Liquid Control (Weekly) . . . Liquid QC is run after weekly . . . maintenance, with each new lot and shipment prior to patient testing . . ." The policy failed to require QC performance each day of patient testing.