

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408585	(X3) Date Survey Completed 05/10/2022
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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review, procedure review, and staff interview, the laboratory failed to ensure testing personnel did not use outdated immunohematology reagents (refer to D5417); failed to perform a positive and negative control each day of patient testing for severe acute respiratory syndrome coronavirus 2 (refer to D5449); failed to perform quality control each day of immunohematology patient testing days (refer to D5451); and failed to test patients for Immunoglobulin M compatibility (refer to D5551). The cumulative effect of these systemic problems limited the laboratory's ability to ensure accurate and reliable patient test results.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on record review, procedure review, and staff interview, the laboratory failed to</p>

ensure testing personnel did not use outdated immunohematology reagents on 2 of 6 patient testing days (01/26 and 02/07) in January and February 2022. The laboratory performed testing for two patients using the outdated immunohematology reagents. Findings include: 1. Reviewed at 4:25 p.m. on 05/09/22, the January and February 2022 immunohematology patient testing and reagent records indicated the laboratory performed patient testing using outdated immunohematology reagents for the following: 01/26/22 Patient #395108 - selectogen screening cells, lot #V5406, expiration date 01/25/22. 02/07/22 Patient #426288 - Anti-Immunoglobulin G, lot #033021001-08, expiration date 02/03/22. 2. Reviewed on 05/10/22, the procedure "Blood Bank Quality Control of Gel Cards and Reagents," effective 05/11/11, stated, ". . . Reagents: Do not use reagents beyond expiration date. . . ." 3. During interview at 11:25 a.m. on 05/10/22, a general supervisor (#2) confirmed the laboratory used outdated reagents for patient immunohematology testing on 01/26/22 and 02/07/22.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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.

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 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) on the GeneXpert System for 19 of 20 patient testing days (February 1-5, 7-11, 13-17, 21, 24, 25, and 28) in February 2022. The laboratory performed 79 SARS-CoV-2 patient tests on days with no quality control (QC) performance. Findings include: 1. Reviewed on 05/10/22, the patient testing records for SARS-CoV-2 on the GeneXpert System indicated performance of patient testing on the following days in February 2022: February 1-5, 7-11, 13-17, 21, 24, 25, and 28. 2. Reviewed on 05/10/22, the February 2022 QC records for SARS-CoV-2 on the GeneXpert System indicated the performance of a positive and negative control on 02/20/22. Upon request on 05/10/22, the laboratory failed to provide evidence of QC performance on February 1-5, 7-11, 13-17, 21, 24, 25, and 28. 3. Reviewed on 05/10/22, the procedure "Flu/RSC [sic]/Covid," for SARS-CoV-2 on the GeneXpert System, effective 08/24/21, stated, ". . . QC Materials & Process: QC is performed every 30 days or new lot or new lot and new shipment. . . ." The policy failed to require QC performance each day of patient testing. 4. During interview at 11:25 a.m. on 05/10/22, a technical supervisor (#1) confirmed the laboratory had failed to perform QC each day of patient testing for SARS-CoV-2 on the GeneXpert System.

D5451

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(iii)(g)

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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256

(g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review, procedure review, and staff interview, the laboratory failed to perform quality control (QC) testing 2 of 4 immunohematology patient testing days (01/14 and 01/28) in January 2022. The laboratory performed immunohematology testing for two patients on the days in January 2022 with no QC performance.

Findings include: 1. Reviewed at 4:25 p.m. on 05/09/22, the January 2022 immunohematology patient testing and QC records indicated the laboratory did not perform QC for immunohematology (blood type, antibody screen, and compatibility) patient testing on the following days: 01/14/22 Patient #426288 01/28/22 Patient #283747 2. Reviewed on 05/10/22, the procedure "Blood Bank Quality Control of Gel Cards and Reagents," effective 05/11/11, stated, "Principle: The purpose of daily quality control (QC) in the blood bank is to confirm the reliability of the test system. . . . Quality Control (QC) must be performed on the day of patient testing. . . . Quality Control: . . . Record results on the laboratory Blood Bank Control Log . . ." 3. During interview at 11:25 a.m. on 05/10/22, a general supervisor (#2) confirmed the laboratory should perform QC each day of patient testing, and the laboratory did not document performance of QC on two patient testing days in January 2022.

D5551

IMMUNOHEMATOLOGY

CFR(s): 493.1271(a)(f)

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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, procedure review, and staff interview, the laboratory failed to test patients for Immunoglobulin (Ig) M compatibility on 6 of 10 patient compatibility testing days (11/29/21, 12/07/21, 12/13/21, 01/10/22, 02/07/22, and 02/28/22) from November 2021-April 2022. The laboratory performed eleven patient tests without IgM compatibility from November 2021-April 2022. Findings include: 1. Reviewed at 4:25 p.m. on 05/09/22, the November 2021-April 2022 immunohematology patient logbook indicated the laboratory did not perform compatibility testing for IgM antibodies on the following days: 11/29/21 Patient #282442 - two tests 12/07/21 Patient #457666 - two tests 12/13/21 Patient #282442 - two tests 01/10/22 Patient #426288 - two tests 02/07/22 Patient #426288 - two tests 02/28/22 Patient #426288 - one test 2. Reviewed on 05/10/22, the procedure "Immediate Spin (IGM) Crossmatch," effective 05/11/11, stated, "Principle: The crossmatch compatibility test is used to detect the presence of blood group antibodies in an intended recipient's serum/plasma directed towards antigens present on donor red blood cells. . . . Interpretation of Results . . . If both Immediate Spin Crossmatch and Antiglobulin Crossmatch are compatible, record as 'compatible' on the Blood Issue and Transfusion

Record. If the unit is incompatible, record 'incompatible' on the Blood Issue and Transfusion Record and also write 'Do Not Use' after this unit. . . ." 3. During interview at 11:25 a.m. on 05/10/22, a general supervisor (#2) confirmed the laboratory should perform immediate spin crossmatch tests for all patient compatibility testing, and the laboratory did not document performance of an immediate spin crossmatch for the above listed patient tests.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:
Based on policy review and staff interview, the laboratory director failed to evaluate and approve performance verification procedures for 2 of 2 newly implemented procedures (high sensitivity troponin and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)) in 2021. The laboratory performed approximately 100 high sensitivity troponin and 500 SARS-CoV-2 patient tests since implementation of the new tests. Findings include: 1. Reviewed on 05/10/22, the policy "Evaluating a New Test," effective 09/01/05, failed to require the laboratory director's approval of the performance verification data for newly implemented tests. An attached, blank form titled "New Method Validation," dated 07/11/16, stated, ". . . When all data has been collected and evaluated as satisfactory, implement the test. Date: ___ Director: ___". 2. Upon request on 05/10/22, the laboratory failed to provide evidence the laboratory director had evaluated and approved the performance verification data for the newly implemented high sensitivity troponin on the Unicel DxC 600i chemistry analyzer and SARS-CoV-2 on the GeneXpert analyzer in 2021. 3. During interview at 11:25 a.m. on 05/10/22, a technical supervisor (#1) confirmed the laboratory did not have evidence the laboratory director had evaluated and approved the performance verification data for the newly implemented high sensitivity troponin and SARS-CoV-2 tests.