

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0656628	(X3) Date Survey Completed 12/06/2024
Name of Provider or Supplier Seiling Municipal Hospital	Street Address, City, State 809 Ne Hwy 60, Seiling, OK	
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
D0000	The recertification survey was performed on 12/03,4,5,6/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant, chief operating officer, and administrator at the conclusion of the survey.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure a proficiency testing attestation statement had been dated by the laboratory director or designee for one of five Hematology events reviewed from 2023 through 2024. Findings include: (1) A review of the first, second, and third 2023; and first and second 2024 Hematology proficiency testing records identified the following for one of five events: (a) Second 2024 Event - The attestation statement had been signed but not dated by the laboratory director or designee. (2) The findings were reviewed with the technical consultant who stated on 12/03/2024 at 1:04 pm, the attestation statement had been signed but not dated by the laboratory director or designee.</p>

<p>D3003</p>	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory failed to ensure 13 of 13 bottles of Thermo Scientific GlucoCrush glucose tolerance beverages were stored to minimize contamination. Findings include: (1) On 12/04/2024 at 10:15 am, observation of the contents of the laboratory refrigerator identified the following materials: (a) Type "O" uncrossmatched units of blood for emergency release; (b) 13 bottles of Thermo Scientific GlucoCrush glucose tolerance beverages for patient consumption. (2) Interview with the technical consultant on 12/04/2024 at 10:20 am confirmed the laboratory failed to minimize contamination by storing patient beverages for consumption with biohazard materials.</p>
<p>D3021</p>	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1)</p> <p>Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory failed to ensure blood products were stored under appropriate conditions in the blood bank refrigerator for three of 34 thermograph charts reviewed between March and November 2024. Findings Include: (1) On 12/03/2024 at 3:45 pm, testing person #1 stated the laboratory maintained two units of O positive and two units of O negative packed red blood cells in the blood bank refrigerator. The units were available for emergency patient transfusions; (2) Observation of the blood bank refrigerator on 12/03/2024 at 3:45 pm identified the refrigerator was connected to an analog temperature recorder which continuously recorded the temperatures for a 7-day period on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade); (3) A review of the 34 temperature charts from 03/01/2024 through 11/15/2024 identified no evidence three of 34 charts had been changed by the 7th day of usage as follows: (a) Between 05/09/2024 and 05/17/2024 (b) Between 08/19/2024 and 08/27/2024 (c) Between 09/17/2024 and 09/19/2024 (4) The findings were reviewed with the technical consultant who stated on 12/06/2024 at 10:15 am, the charts had not been changed by the 7th day of usage as shown above.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:
 Based on a review of records, written policies and procedures, and interview with the technical consultant, the laboratory failed to assess the competency of the technical consultant based on the position responsibilities as listed in subpart M, and the policy failed to define the frequency the assessments were to be performed. Findings include: (1) A review of the laboratory policy and procedure manual identified a written policy for assessing the competency of the technical consultant based on the position responsibilities. The policy did not define the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of March 2023 through the current date identified competencies based on the position responsibilities, had not been performed for the technical consultant listed on the CMS-209; (3) The findings were reviewed with the technical consultant who stated on 12/03/2024 at 02:28 pm, competency assessments had not been performed for the technical consultant during the review period, and the policy failed to define the frequency of assessments as stated above.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results to identify biases for one of five Hematology proficiency testing events reviewed in 2023 and 2024. Findings include: (1) On 12/03/2024, a review of Hematology proficiency testing records for 2023 (first, second, and third events) and 2024 (first and second events) identified the following biases (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program) for one of five events: (a) First 2024 Event: (i) Hematocrit (Hem-5S) - five of five results exhibited positive biases: (aa) Sample XE-01 - SDI of -0.7 (bb) Sample XE-02 - SDI of -2.0 (cc) Sample XE-03 - SDI of -2.0 (dd) Sample XE-04 - SDI of -1.3 (ee) Sample XE-05 - SDI of -1.2 (2) There was no evidence in the records to prove the biases had been identified and addressed; (3) The records were reviewed with the technical consultant who stated on 12/03/2024 at 01:40 pm, the biases had not been addressed.

D5401

PROCEDURE MANUAL
 CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
 Based on a review of records, written policy, and interview with the technical consultant, the laboratory failed to follow the written policy to ensure that emergency

release of blood forms had been signed by the physician for one of three emergency releases reviewed; and failed to follow written policy for compatibility testing as soon as possible after emergency release for one of two units given. Findings include: Emergency Release Forms (1) On 12/06/2024 at 11:00 am, the technical consultant stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for emergency transfusions; (2) A review of the policy titled, "Emergency Release of uncrossmatched units" required an Emergency Release form be completed (OBI_CL_Form 257). The form included a space for the medical provider's signature. The policy also stated "If a PA or APRN signs OBI_CL_Form 257, accepting responsibility for the transfusion, the form must be returned to the facility and additionally signed by a hospital physician"; (3) A review of documentation of emergency issue identified the following for one of three patient records: (a) One unit of O positive packed red blood cells had been released to a patient on 10/25/2024. The "Emergency Blood Transfusion Request" form appeared to be signed by a mid-level provider and not a physician; (4) The documentation was reviewed with the technical consultant who stated on 12/06/2024 at 11:00 am, the emergency releases had not been signed by a physician. Emergency Release Compatibility Testing (1) On 12/06/2024 at 11:00 am, the technical consultant stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for emergency transfusions; (2) A review of the policy titled, "Emergency Release of uncrossmatched units" stated, "This procedure provides instructions when emergency transfusion is medically necessary before compatibility testing can be performed by the reference laboratory". The policy also stated "When the appropriately labeled specimen is received in the reference laboratory, the standard compatibility testing procedure will be completed with a stat priority status"; (3) A review of documentation of emergency releases identified the following for one of two patient records: (a) Unit # W091024203484 - O positive packed red blood cells had been emergency released to a patient on 5/1/2024, with no documentation of compatibility testing performed after release. (4) The documentation was reviewed with the technical consultant who stated on 12/06/2024 at 11:00 am, the sample had not been sent to the reference laboratory for compatibility testing after the emergency release.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
 Based on a review of written policies and procedures, and interview with the technical consultant and testing person #1, the laboratory failed to have complete written quality control policies and procedures for one of four test systems reviewed. Findings include: (1) On 12/03/2024 at 10:40 am, the technical consultant and testing person #1 stated the following: (a) The laboratory performed Albumin, Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase, Aspartate Aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium, Creatinine Kinase (CK), Chloride, Creatinine, CO2, Glucose, High-Density Lipoprotein (HDL), Potassium, Lactic Acid, Lipase, Magnesium, Sodium, Total Bilirubin, Total Protein, Triglyceride, Acetaminophen, Alcohol, Digoxin, and Salicylic Acid testing using the Ortho Vitro XT3400 analyzer; (2) On 12/05/2024, a review of chemistry policies and procedures titled, "Chemistry Analysis Using the Ortho Vitros XT3400 System" did not include the following quality control procedures: (a) Type of control, including manufacturer's name; (b) Identify (i.e., normal, abnormal, Level I, II, etc.); (c) Number and frequency of testing controls; (d) Establishing control limits (mean and ranges) with new lot numbers; (e) Criteria to determine acceptable control results. (3) The findings were reviewed with the technical consultant who stated on 12/05/2024 at 04:30 pm, the chemistry procedure did not include all of the required information.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:
 Based on observation and interview with the technical consultant, the laboratory failed to ensure expired reagents were not available for use. Findings include: (1) Observation of the reagent freezer located in the draw room on 12/03/2024 at 04:10 pm, identified the following expired reagents were available for use: (a) Three boxes of Isozyme Performance Verifier I - CKMB, CK, lot R9818, expired 09/12/2024 (b) Three boxes of Isozyme Performance Verifier II - CKMB, CK, lot T9820, expired 09/12/2024 (2) Interview with the technical consultant on 12/04/2024 at 10:50 am confirmed the expired reagents were available for use.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for two of two analyzers. Findings include: OPTIMEDICAL CCA-TS2 (1) On 12/03/2024 at 04:02 pm, the

technical consultant stated the laboratory performed blood gas testing using the OPTIMedical CCA-TS2 analyzer; (2) A review of the manufacturer's instruction manual titled, "OPTIMedical CCA-TS2 Analyzer Operator's Manual", under section 7.2 identified the following required weekly maintenance procedure: (a) "Once a week, the Sample Measurement Chamber (SMC) must be cleaned." (3) A review of maintenance logs from April 2024 through October 2024 identified weekly maintenance had not been documented as performed between 05/02/2024 and 05/13/2024; (4) The records were reviewed with the technical consultant who stated on 12/05/2024 at 10:41 am, the weekly maintenance procedure had not been documented as performed as stated above. SYSMEX XN450 (1) On 12/03/2024 at 04:15 pm, the technical consultant stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XN-450 analyzer; (2) A review of the manufacturer's instruction manual titled, "XN-L Series XN-550/XN-450/XN-350 - Troubleshooting", section 2.17 Maintenance and Inspection Checklist showed the following required maintenance procedures: (a) "Weekly - Routine Cleaning" (3) A review of maintenance logs from January 2024 through October 2024 identified weekly maintenance had not been documented as performed between 02/20/2024 and 03/05/2024; (4) The records were reviewed with the technical consultant who stated on 12/05/2024 at 11:00 am, the weekly maintenance procedure had not been documented as performed as stated above.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the laboratory failed to perform calibration verification procedures at least once every six months for one of three test systems during the review period of March 2023 through the current date. Findings include: (1) On 12/03/2024 at 04:02 pm, the technical consultant stated the laboratory performed blood gas testing using the OPTIMedical CCA-TS2 analyzer; (2) On 12/04/2024, a review of calibration records from March 2023 through the current date identified no evidence calibration verification had been

performed at least once every six months after 03/12/2024; (3) The records were reviewed with the technical consultant who stated on 12/04/2024 at 04:11 pm, calibration verification procedures had not been performed every six months as stated above.

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant and testing person #1, the laboratory failed to perform two levels of quality control materials each eight hours of patient D-dimer testing for two of 15 days reviewed. Findings include: (1) On 12/04/2024 at 02:20 pm, the technical consultant and testing person #1 stated the following: (a) The laboratory performed D-dimer testing using the Quidel Triage MeterPro analyzer; (b) The laboratory performed two levels of QC (Quality Control) materials each eight hours of patient testing; (c) An IQCP (Individualized Quality Control Plan) had not been developed for the test system. (2) On 12/04/2024, a review of QC and patient testing records for testing performed during June and October 2024 identified two levels of QC materials had not been performed each 8 hours of patient testing (QC had not been performed on the days of testing) for two of 15 days as follows: (a) On 08/24/2024 - testing was performed on sample with patient ID #51874; (b) On 08/25/2024 - testing were performed on samples with Patient IDs #51904 and #51913. (3) The records were reviewed with the technical consultant who stated on 12/04/2024 at 02:58 pm, two levels of QC materials had not been performed each eight hours of patient testing.

D5553

IMMUNOHEMATOLOGY
CFR(s): 493.1271(b)(f)

(b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (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 a review of records, written policy, and interview with the technical consultant, the laboratory failed to comply with 21 CFR 606.160(b)(3)(v). The laboratory failed to ensure that emergency release of blood forms had been signed by the physician for one of three emergency releases reviewed. Findings include: (1) On 12/06/2024 at 11:00 am, the technical consultant stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for patient transfusions; (2) On 12/06/2024 a review of the policy titled, "Emergency Release of uncrossmatched units" required an Emergency Release form be completed (OBI_CL_Form 257). The form included a space for the medical provider's signature. The policy also stated "If a PA or APRN signs OBI_CL_Form 257, accepting

responsibility for the transfusion, the form must be returned to the facility and additionally signed by a hospital physician"; (3) A review of documentation of emergency issue identified the following for one of three patient records: (a) One unit of O positive packed red blood cells had been released to a patient on 10/25/2024. The "Emergency Blood Transfusion Request" form appeared to be signed by a mid-level provider and not a physician; (4) The documentation was reviewed with the general supervisor who stated on 12/06/2024 at 11:00 am, the emergency releases had not been signed by a physician.