

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0470045	(X3) Date Survey Completed 08/30/2024
Name of Provider or Supplier Arbuckle Memorial Hospital	Street Address, City, State 2011 W Broadway Ave, Sulphur, 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 08/28,29,30/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, laboratory manager, testing person #3, chief executive officer, and director of clinical resource during an exit conference performed 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 laboratory manager, the laboratory director or designee failed to sign proficiency testing attestation statements for six of 17 events reviewed in 2023 and 2024. Findings include: (1) On 08/29/2024, a review of 2023 and 2024 proficiency testing events identified the following for six of 17 events: (a) Second Chemistry Core Event 2023 - The attestation statement had not been signed by the laboratory director or designee; (b) Second Hematology /Coagulation Event 2023 - The attestation statement had not been signed by the laboratory director or designee; (c) Second Immunology/Immunoematology Event 2023 - The attestation statement had not been signed by the laboratory director; (d)</p>

Second Chemistry Miscellaneous Event 2023 - The attestation statement had not been signed by the laboratory director or designee; (e) Third Hematology/Coagulation Event 2023 -The attestation statement had not been signed by the laboratory director or designee; (f) Third Immunology/Immunohematology Event 2023 - The attestation statement had not been signed by the laboratory director. (2) The findings were reviewed with the laboratory manager who stated on 08/28/2024 at 01:10 pm the attestation statements had not been signed by the laboratory director or designee (as applicable).

D3025

REQUIREMENTS FOR TRANSFUSION SERVICES
CFR(s): 493.1103(d)

Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

This STANDARD is not met as evidenced by:
Based on a review of records, hospital policy, and interview with the clinical laboratory director and nursing director the laboratory failed to ensure written policies were followed for preventing transfusion reactions for one of three patients transfused. Findings include: (1) On 08/28/2024 at 09:30 am, the laboratory manager stated that blood transfusions were performed by nursing staff; (2) On 08/29/2024, a review of the hospital policy titled, "Blood Products Administration" stated all adult patient shall have vital signs taken as follows:" (a) "Prior to the start of the transfusion" (b) "Q 5 minutes there after X 4 after the transfusion is started" (c) "Q 15minutes X 4" (d) "Then Q 30 minutes until transfusion is completed" (e) "Post transfusion" (3) A review of transfusion records for one unit identified the policy had not been followed: (a) Unit #155428 - The unit was started on 03/19/2024 at 04:55 pm and vital signs had not been documented as performed as follows: (i) One 15 minute vital had not been documented between 05:30 pm and 06:00 pm (4) The records were reviewed with the clinical nursing director who stated on 08/30/2024 at 11:30 am, the vital signs had not been documented according to policy.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
Based on interview with the laboratory manager and testing person #6, the laboratory failed to provide written instructions to clients collecting and referring specimens for testing performed in the laboratory. Findings include: (1) On 08/28/2024 at 09:45 pm, the laboratory manager and testing person #6 stated the following testing were performed and specimens were transported to the laboratory from nursing homes and home health care agencies: (a) CBC (complete blood count) testing using the Sysmex XN-550 analyzer; (b) Routine Chemistry testing using the Siemens Dimension EXL with LM and Dimension EXL 200 analyzers. (2) Interview with the laboratory manager and testing person #6 on 08/28/2024 at 11:09 am confirmed the laboratory

	<p>did not provide written instructions (i.e., client service manual) to the clients to explain the laboratory's specimen collection and transportation policies.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of written procedures and interview with the laboratory manager, the laboratory failed to ensure two of three procedures had been approved, signed, and dated by the current laboratory director. Findings include: WET PREP (1) On 08/29 /2024 at 11:20 am, the laboratory manager stated the laboratory performed wet prep procedure to examine the presence of yeasts, Trichomonas vaginalis, and clue cells using vaginal secretion; (2) A review of the procedure titled, "Wet Prep" identified no indication it had been approved, signed, and dated by the current laboratory director; (3) The findings were reviewed with the laboratory manager who stated on 08/29 /2024 at 11:26 am, the procedure had not been signed and dated by the current laboratory director. SERUM HCG (1) On 08/29/2024 at 11:22 am, the laboratory manager stated the laboratory performed qualitative hCG (Human chorionic gonadotropin) testing using serum specimens; (2) A review of the procedure for the serum hCG identified no indication it had been signed and dated as approved by the laboratory director; (3) The findings were reviewed with the laboratory manager who stated on 08/29/2024 at 11:26 am, the procedure had not been signed and dated by the laboratory director.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager and testing person #6, the laboratory failed to label three of three containers with the identity, expiration date, and lot number of the contents. Findings include: (1) On 08/28/2024 at 10:40 am, the laboratory manager and testing person #6 stated the laboratory stained peripheral blood smears to perform manual differential testing; (2) Observation on 08 /28/2024 at 10:45 am identified three unlabeled Copeland jars, appearing to contain materials used to stain peripheral blood smears; (3) The findings were reviewed with testing person #6 and the laboratory manager who stated on 08/28/2024 at 11:06 am the Copeland jars contained staining materials had not been labeled with the identity, expiration date, and lot numbers.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</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.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure expired blood bank reagents were not available for use for one of 15 days of patient testing reviewed from January 2024 through July 2024. Findings include: (1) On 08/29/2024 at 01:25 pm, the laboratory manager stated Crossmatch testing was performed in the laboratory which included ABO Typing and Antibody Screen testing using the tube method; (2) On 08/30/2024, a review of quality control and patient testing records for 15 days of patient testing performed from 01/29/2024 through 07/27/2024 showed expired reagents had been used for patient testing on 02/03/2024: (a) Immucor Reagent Red Blood Cells A1 and B; lot #111490 with an expiration date 02/02/2024; (b) Immucor Reagent Red Blood Cells PanoScreen I, II, and III; lot #48793 with an expiration date of 02/02/2024. (3) The records were reviewed with the laboratory manager who stated on 08/30/2024 at 11:10 am, the documentation showed expired reagents had been used on the date of testing.

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 and interview with the laboratory manager, testing person #3, and testing person #6, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the OPTI CCA-TS blood gas analyzer during the review period of January 2023 through July 2024. Findings include: (1) On 08/28/2024 at 09:30 am, the laboratory manager and testing person #6 stated the laboratory performed blood gas testing using the OPTI CCA-TS analyzer; (2) A review of the manufacturer's instruction manual titled, "OPTI CCA-TS Procedure Manual", under section 6.3 identified the following required quarterly maintenance procedures: (a) "Perform the tHb calibration (Refer to the calibration section of this procedures)." (3) A review of maintenance logs from January 2023 through July 2024 identified quarterly maintenance had not been documented as performed between 07/23/2023 and 01/27/2024: (4) The records were reviewed with the laboratory director and testing person #3 who stated on 08/30/2024 at 10:36 am, the maintenance procedure had not been documented as performed.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the laboratory manager, the laboratory failed to follow their policy for monitoring the effectiveness of their QCP (Quality Control Plan) for two of three test systems reviewed from January 2023 through the current date. Findings include: D-DIMER (1) On 08/28/2024 at 10:50 am, the laboratory manager stated the following: (a) The laboratory performed D-dimer testing using Alere Triage Meter Pro analyzer; (b) An IQCP (Individualized Quality Control Plans) had been developed for the test system. (2) A review of the IQCP for the test system identified that QA (Quality Assessment) reviews of the QCP (Quality Control Plan) were to be performed on an annual basis; (3) A review of records for the test system from January 2023 through the current date identified no documentation that annual QA reviews had been performed since 01/04/2023; (4) The records were reviewed with the laboratory manager who stated on 08/29/2024 at 01:25 pm, annual QA reviews had not been documented as performed as stated above. PT/INR AND PTT (1) On 08/28/2024 at 10:50 am, the laboratory manager stated the following: (a) The laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) using Hemochron Signature Elite analyzer; (b) An IQCP (Individualized Quality Control Plans) had been developed for the test system. (2) A review of the IQCP for the test system identified that QA (Quality Assessment) reviews of the QCP (Quality Control Plan) were to be performed on an annual basis; (3) A review of records for the test system from January 2023 through the current date identified no documentation that annual QA reviews had been performed since 01/04/2023; (4) The records were reviewed with the laboratory manager who stated on 08/29/2024 at 01:25 pm, annual QA reviews had not been documented as performed as stated above.

D5807

TEST REPORT
 CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the laboratory manager and testing person #6, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population for two of two patient reports reviewed. Findings include: (1) On 08/28/2024 at 10:00 am, testing person #6 stated the laboratory performed CBC (complete blood count) testing using the Sysmex XN-550 analyzer; (2) On 08/29/2024 two patient CBC reports were reviewed - the first report was for an adult female patient with the testing performed on 08/28/2024 at 18:43 pm; the second report was for an adult male patient with the testing performed on 08/29/2024 at 10:41 am. Both reports included the same reference intervals for the following CBC parameters: (a) Hemoglobin - 11.5 - 17.0 g/dL; (b) Hematocrit - 37.0 - 54.0 %. (3) The reports were reviewed with the laboratory manager who stated on 08/30/2024 at 10:50 am, the patient reports did not include gender specific reference ranges for hemoglobin and hematocrit.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for five of 17 proficiency testing events reviewed in 2023 and 2024. Findings include: (1) On 08/29/2024, a review of 2023 and 2024 proficiency testing events identified attestation statements had been signed up to seven months after the samples had been tested for five of 17 events reviewed: (a) First Chemistry Miscellaneous Event 2024 - The sample testing had been completed on 05/08/2024 and the attestation statement had not been signed by the laboratory director until 08/26/2024; (b) First Chemistry Core Event 2024 - The sample testing had been completed on 01/30/2024 and the attestation statement had not been signed by the laboratory director until 08/26/2024; (c) First Hematology/Coagulation Event 2024 - The sample testing had been completed on 03/21/2024 and the attestation statement had not been signed by the laboratory director until 08/24/2024; (d) First Immunology /Immunohematology Event 2024 - The sample testing had been completed on 04/02/2024 and the attestation statement had not been signed by the laboratory director until 08/26/2024; (e) Second Chemistry Core Event 2024 - The sample testing had been completed on 06/18/2024 and the attestation statement had not been signed by the laboratory director until 08/24/2024. (2) The records were reviewed with the laboratory manager who stated on 08/28/2024 at 01:10 pm the attestation statements had not been signed timely as stated above.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of one testing person. Findings include: (1) On 08/28/2024 a review of personnel records for one person hired to perform moderate complexity testing after the previous recertification survey identified the following for one of one person: (a) Testing Person #8 - The initial training was complete on 05/31/2023. There was no evidence a competency evaluation had been performed between 05/31/2023 and 08/24/2024. (2) The records were reviewed with the laboratory manager who stated on 08/30/2024 at 10:10 am, a semiannual competency evaluation had not been performed.

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 a review of records and interview with the laboratory manager, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for six of six persons performing testing during 2022 and to date in 2024. Findings include: (1) On 08/28/2024 a review of personnel records for six persons performing moderate complexity testing during 2022 and to date in 2024 identified no evidence an annual competency evaluation had been performed for six of six testing persons as follows: (a) Testing Person #2 - Between 08/26/2022 and 08/26/2024 (b) Testing Person #3 - Between 08/26/2022 and 08/24/2024 (c) Testing Person #4 - Between 08/26/2022 and 08/26/2024 (d) Testing Person #5 - Between 08/26/2022 and 08/24/2024 (e) Testing Person #6 - Between 08/26/2022 and 08/26/2024 (f) Testing Person #7 - Between 08/26/2022 and 08/24/2024 (2) The records were reviewed with the laboratory manager who stated on 08/30/2024 at 10:10 am the annual evaluations had not been performed.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the technical supervisor failed to ensure competency evaluations for high complexity testing had been performed semiannually during the first year of testing for one of one testing person. Findings include: (1) On 08/28/2024 a review of personnel records for one person hired to perform high complexity testing after the previous recertification survey identified the following for one of one person: (a) Testing Person #8 - The initial training was complete on 05/31/2023. There was no evidence a competency evaluation had been performed between 05/31/2023 and 08/24/2024. (2) The records were reviewed with the laboratory manager who stated on 08/30/2024 at 10:10 am, a semiannual competency evaluation had not been performed. Note: High complexity testing included ABO/Rh typing, Antibody Screen, and Compatibility testing.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the technical supervisor failed to ensure personnel performing high complexity testing had been evaluated at least annually for six of six persons performing testing during 2022 and to date in 2024. Findings include: (1) On 08/28/2024 a review of personnel records for six persons performing high complexity testing during 2022 and to date in 2024 identified no evidence an annual competency evaluation had been performed for six of six testing persons as follows: (a) Testing Person #2 - Between 08/26/2022 and 08/26/2024 (b) Testing Person #3 - Between 08/26/2022 and 08/24/2024 (c) Testing Person #4 - Between 08/26/2022 and 08/26/2024 (d) Testing Person #5 - Between 08/26/2022 and 08/24/2024 (e) Testing Person #6 - Between 08/26/2022 and 08/26/2024 (f) Testing Person #7 - Between 08/26/2022 and 08/24/2024 (2) The records were reviewed with the laboratory manager who stated on 08/30/2024 at 10:10 am the annual evaluations had not been performed. Note: High complexity testing included ABO/Rh typing, Antibody Screen, and Compatibility testing.