Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472705	04/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Okeene Municipal Hospital	207 East F Street, Okeene, 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 04/22,23,24,25/2025. The laboratory was found out of compliance with the following CLIA Conditions: 493.1213; D5022: Toxicology, High Complexity 493.1441; D6076: Laboratory Director, High Complexity The findings were reviewed with the laboratory director, testing person #1, and finance manager during an exit conference performed at the conclusion of the survey.
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, nursing policy, and interview with testing person #1 and chief nursing officer, the facility failed to ensure written policies were followed for preventing transfusion reactions for one of two units of packed red-blood cells transfused. Findings include: (1) On 02/24/2025 at 04:00 pm, testing person #1 and testing person #2 stated blood transfusions were performed by nursing staff; (2) A review of the hospital policy titled, "Blood Administration, Blood Product Administration, Reaction Symptoms, Documentation, Consents/Refusals, and COVID 19 Convalescent Plasma Administration" under section B "Transfusion Procedures (PRBC, Whole Blood)" stated the following: (a) "Obtain base line vital signs and place on Vital signs flowsheet in EPIC"; (b) "Vital signs will be taken every 10 minutes during the first 30 minutes of infusion watching for transfusion reaction symptoms"; (c) "After the first 30 minutes, the patient should be assessed frequently and vital signs taken every 30 minutes and documented on the vital signs flowsheet in EPIC for the duration of the transfusion." (3) A review of transfusion records for two

	units transfused, identified the policy had not been followed for taking vitals for one of two units transfused as follows: (a) Unit #W090124373845 - The transfusion began on 01/04/2025 at 04:36 pm and was completed on 01/04/2025 at 07:02 pm: (i) Vitals every ten minutes for the first 30 minutes - There was no documentation 10-minute vitals had been taken between 04:36 and 04:59 pm; (ii) Vitals Every 30 Minutes for the duration of the transfusion - There was no documentation vitals had been taken between 06:01 and 07:02 pm. (4) The findings were reviewed with the chief nursing officer who stated on 04/24/2025 at 04:35 pm, the vital signs had not been documented according to policy.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, urine drug screen package inserts, FDA database, email correspondence with FDA representative, and interview with the laboratory director and testing person #1, the laboratory failed to ensure the requirements were met for the subspecialty of toxicology for five of five months of patient testing. Findings include: (1) The laboratory failed to verify the accuracy for the Clearrapids Drug Test Card -12 Panel Drug Test Card at least twice annually. Refer to D5217; (2) The laboratory failed to establish the performance specifications for the Clearrapids Drug Test Card -12 Panel Drug Test Card not cleared or approved by the FDA. Refer to D5423; (3) The laboratory failed to perform a negative and positive control material each day of patient urine drug screen testing. Refer to D5449.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and testing person #1, the laboratory failed to verify the accuracy for one of one test method at least twice annually during the review period of November 2024 through the current date. Findings include: (1) On 04/22/2025 at 02:45 pm, testing person #1 stated the laboratory performed urine drug screen testing using the Clearrapids Drug Test Card -12 Panel Drug Test Card which included the following analytes; (a) Amphetamine (AMP) (b) Barbiturates (BAR) (c) Buprenorphine (d) Benzodiazepines (BZO) (e) Cocaine (COC) (f) Marijuana (THC) (g) Methylenedioxymethamphetamine (MDMA) (h) Methamphetamine (MET) (i) Oxycodone (OXY) (j) Phencyclidine (PCP) (k) Opiates (MOP) (l) Methadone (MTD) (2) A review of 2024 and 2025 proficiency testing records identified the laboratory had not enrolled and participated in proficiency testing for the above analytes, therefore, it was determined the laboratory must verify the accuracy of the testing at least twice annually; (3) Interview with the testing person 04/23/2025 at 04:10 pm confirmed the laboratory did not have a method in place to verify the accuracy of the testing at least twice annually and it had

	not been verified during the review period of November 2024 through the current date because it was believed the test kit was categorized as waived; (4) The following were examples of patient testing performed on the Clearrapids Drug Test Card - 12 Panel Drug Test Card: (a) Specimen ID OOMH243070011 - testing performed on 11/02 /2024 (b) Specimen ID OOMH243110024 - testing performed on 11/06/2024 (c) Specimen ID OOMH243150003 - testing performed on 11/10/2024 (d) Specimen ID OOMH243230037 - testing performed on 11/18/2024 (e) Specimen ID OOMH243270034 - testing performed on 11/22/2024 (f) Specimen ID OOMH243370096 - testing performed on 12/02/2024 (g) Specimen ID OOMH243450053 - testing performed on 12/10/2024 (h) Specimen ID OOMH243460052 - testing performed on 12/11/2024 (i) Specimen ID OOMH250040012 - testing performed on 01/04/2025 (j) Specimen ID OOMH250150048 - testing performed on 01/15/2025 (k) Specimen ID OOMH250260008 - testing performed on 01/26/2025 (l) Specimen ID OOMH250270067 - testing performed on 01/27/2025 (m)Specimen ID OOMH250280050 - testing performed on 01/28/2025 (n) Specimen ID OOMH250350026 - testing performed on 02/04/2025 (o) Specimen ID OOMH250380039 - testing performed on 02/07/2025 (p) Specimen ID OOMH250440026 - testing performed on 02/13/2025 (q) Specimen ID OOMH250540016 - testing performed on 02/23/2025 (r) Specimen ID OOMH250550068 - testing performed on 02/24/2025 (s) Specimen ID OOMH250570016 - testing performed on 02/26/2025 (t) Specimen ID OOMH250590046 - testing performed on 02/28/2025 (u) Specimen ID OOMH250590046 - testing performed on 02/28/2025 (v) Specimen ID OOMH250630007 - testing performed on 03/04/2025 (w) Specimen ID OOMH250700060 - testing performed on 03/11/2025 (x) Specimen ID OOMH250780043 - testing performed on 03/19/2025 (y) Specimen ID OOMH250840044 - testing performed on 03/25/2025 (z) Specimen ID OOMH250890005 - testing performed on 03/30/2025 (aa) Specimen ID OOMH250940020 - testing performed on 04/04/2025 (bb) Specimen ID OOMH25097003 - testing performed on 04/07/2025 (cc) Specimen ID OOMH250980073 - testing performed on 04/08/2025 (dd) Specimen ID OOMH251030019 - testing performed on 04/13/2025 (ee) Specimen ID OOMH251060031 - testing performed on 04/16/2025 (ff) Specimen ID OOMH251090016 - testing performed on 04/19/2025
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 written policies and procedures and interview with testing person #1, the laboratory failed to follow written procedures for blood bank alarm checks during the review period of May 2023 through January 2025. Findings include: (1) On 04/22/2025 at 03:15 pm, testing person #1 stated the laboratory routinely maintained two units of O negative and two units of O positive PRBCs (Packed Red Blood Cells) in the Helmer blood bank refrigerator. The units were available for emergency patient transfusions (PRBCs must be stored at 1-6 degrees

	Celsius); (2) On 04/24/2025, a review of the laboratory's written policy, titled, "Blood Bank Alarm" under the section "Principle" required the alarm checks be performed three times a year; (3) A review of the alarm check records from May 2023 through January 2025 identified the alarm checks had not been performed three times a year in 2024 (it had only been documented as performed on 03/12/2024 and 09/10/2024); (4) Interview with the laboratory director on 04/24/2025 at 03:27 pm confirmed that the laboratory had not followed it's written policy for performing blood bank alarm checks three times a year as stated above.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 policies and procedures and interview with testing person #1 and the finance manager, the laboratory failed to have complete written quality control policies and procedures for chemistry testing. Findings include: On 04/22/2025 at 03: 45 pm, testing person #1 stated Chemistry testing which included the analytes Albumin, ALP (Alkaline Phosphatase), ALT (Alanine Aminotransferase), Amylase, AST (Aspartate Aminotransferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CK (Creatine Kinase), CO2, Creatinine, Free T4, Glucose, HDL (high Density Lipoprotein) Cholesterol, LDH (Lactate Dehydrogenase), Lipase, Magnesium, Potassium, PSA (Prostate Specific Antigen), Sodium, Direct Bilirubin, Total Bilirubin, Total Protein, Triglycerides, TSH (Thyroid Stimulating Hormone), Troponin, and Lactic Acid using the Vitro 5600 analyzer; (2) A review of the policy and procedure manual for chemistry identified no evidence of a procedure describing the method for establishing means and ranges for new lot numbers of QC (Quality Control) materials; (3) The findings were reviewed with testing person #1 and the finance manager who stated on 04/24/2025 at 11:09 am, the laboratory did not have a written policy and procedure for establishing means and ranges for new lot numbers of QC materials.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)

	(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of records, urine drug screen package inserts, FDA database, email correspondence with FDA representative, and interview with the laboratory director and testing person #1, the laboratory failed to establish the performance specifications for the Clearrapids Drug Test Card -12 Panel Drug Test Card not categorized by the FDA. Findings include: (1) On 04/22/2025 at 02:45 pm, testing person #1 stated the laboratory performed patient urine drug screen using the Clearrapids Drug Test Card -12 Panel Drug Test Card test; (2) A review of the FDA (Food and Drug Administration) test classification database did not include a classification for the test kit (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the categorization of the test as high complexity). This was also confirmed during email correspondence with an FDA representative on 04/23/2025; (3) Interview with testing person #1 on 04/23/2025 at 10:00 am confirmed the test kit had been put into use for patient testing on or around November 2024; (4) A review of records for the test system revealed no evidence the performance specifications of accuracy, precision, analytical sensitivity, analytical specificity, reportable range, and reference intervals as applicable, had been established prior to putting the test into use for patient testing; (5) The findings were reviewed with laboratory director and testing person #1, who stated on 04/24/2025 at 10:00 am the laboratory did not establish the performance specifications prior to putting the test kit into use because it was believed the test kit was categorized as waived; (6) Refer to D5217 for examples of patient urine drug screen testing performed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 testing person #1 and laboratory director, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the OPTI CCA-TS2 blood gas analyzer during the review period of January 2024 through March 2025. Findings include: (1) On 04/22/2025 at 02:45 pm, testing person #1 stated the laboratory performed arterial blood gas testing using the OPTI CCA-TS2 analyzer; (2) On 04/23/2025, a review of the manufacturer's instructions manual titled, "OPTI CCA-TS2 Analyzer Operator's Manual", under section 7.4 required the following annual maintenance procedures: (a)

	Replace the peristaltic pump cartridge (b) Replace gas I/O port (3) A review of maintenance logs from January 2024 through March 2025 identified the following: (a) Gas I/O port - Not documented as performed during the review period. (4) The records were reviewed with the laboratory director who stated on 04/23/2025 at 02:30 pm, maintenance procedures had not been documented as performed.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policy and procedure, and interview with the laboratory director, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for four of four function checks performed during the review period of May 2023 through the current date. Findings include: (1) On 04 /22/2025 at 04:25 pm, testing person #2 stated the laboratory performed microscopic urine sediment examination and the specimens were processed using the Unico PSS 602 centrifuge at a speed of 1500 rpm (revolutions per minute) for five minutes; (2) A review of the centrifuge function check policy titled, "Centrifuge Maintenance" required that the centrifuge's speed and timer be checked at 1500 +/- 100 rpm for five minutes +/- 10% every six months; (3) On 04/23/2025, a review of centrifuge records from May 2023 through the current date identified the centrifuge speed had not been checked at the speed urines were processed and/or the actual speed and time obtained had not been documented for four of four checks performed as follows: (a) 05/23 /2023 - The speed had been checked at 2062 rpm; (b) 11/17/2023 - The actual speed and time obtained had not been recorded; (c) 05/22/2024 - The speed had been checked at 2062 rpm; (d) 11/13/2024 - The speed had been checked at 1958 rpm. (4) The records were reviewed with the laboratory director who stated on 04/23/2024 at 02:00 pm, the laboratory had not followed their policy for ensuring the centrifuge was functioning properly as stated above.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and testing person #1, the laboratory failed to perform a negative and positive control materials for 49 of 50 days of patient urine drug screen testing. Findings include: (1) On 04/22 /2025 at 02:45 pm, testing person #1 stated the laboratory performed urine drug screen using the Clearrapids Drug Test Card -12 Panel Drug Test Card for patient testing; (2) A review of QC (Quality Control) and patient testing records from November 2024 through the current date identified negative and positive QC materials had not been performed each day of patient testing for 49 of 50 days of patient testing and there

	was no evidence an IQCP (Individualized Quality Control Program) had been developed; (3) On 04/24/2025 at 09:45 am, testing person #1 stated the laboratory performed negative and positive QC materials monthly and with each new lot of test kit because it was believed the test kit was categorized as waived; (4) Refer to D5217 for examples of patient urine drug screen testing performed.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) 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 director, 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 two of three proficiency testing events reviewed in 2024 in immunology /immunohematology. Findings include: (1) A review of 2024 proficiency testing events identified attestation statements had been signed up to three months after the samples had been tested for two of three events reviewed: (a) Second Immunology /Immunohematology Event 2024 - The sample testing had been completed on 08/12 /2024 and the attestation statement had not been signed by the laboratory director until 09/05/2024; (b) Third Immunology/Immunohematology Event 2024 - The sample testing had been completed on 12/03/2024 and the attestation statement had not been signed by the laboratory director until 03/11/2025. (2) The records were reviewed with the laboratory director who stated on 04/23/2025 at 02:00 pm the attestation statements had not been signed timely as stated above.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, urine drug screen package inserts, FDA database, email correspondence with an FDA representative, and interview with the laboratory director and testing person #1, the laboratory director failed to provide overall management and direction for a urine drug screen test for five of five months of testing. Findings include: (1) The laboratory director failed to ensure the Clearrapids Drug Test Card - 12 Panel Drug Test Card provided quality results for patient care for five of five months of testing. Refer to D6085.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) (e)(3) Ensure that-- (e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

	This STANDARD is not met as evidenced by: Based on a review of records, urine drug screen package inserts, FDA database, email correspondence with FDA representative, and interview with the laboratory director and testing person #1, the laboratory director failed to ensure a urine drug screen test provided quality results for patient care for five of five months of patient testing. Findings include: (1) The laboratory director failed to ensure the FDA categorization of the Clearrapids Drug Test Card - 12 Panel Drug Test Card prior to using for patient testing. Refer to D5217, D5423, and D5449.