Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472771	03/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Harper County Community Hospital	1003 Hwy 64 North, Buffalo, 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 03/25,26,27,28/2025. 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 chief executive officer, laboratory director, technical consultant, and testing person #3 at the conclusion of the survey.
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 insert and test kit box, FDA database, email correspondence with an FDA representative, and interview with the technical consultant and laboratory manager, the laboratory failed to ensure the requirements were met for the subspecialty of Toxicology for nine of nine months of patient testing. Findings include: (1) The laboratory failed to have written policy defining the method to verify the accuracy of the urine drug screen testing at least twice annually. Refer to D5401; (2) The laboratory failed to establish the performance specifications for the Accurate Urine DOA Rapid Test Dipcard test not cleared or approved by the FDA. Refer to D5423; (3) The laboratory failed to perform a negative and positive control material 14 of 14 days of patient urine drug screen testing. Refer to D5449.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with testing person #3, the laboratory failed to document competency assessments of the clinical consultant and technical consultants, based on the position responsibilities as listed in Subpart M, for one of one clinical consultant and for two of two technical consultants. Findings include: (1) On 03/25/2025 at 2:00 pm, a review of written policies identified no evidence of competency assesments for the clinical consultant and two technical consultants; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of April 2023 through the current date identified competencies, based on job responsibilities, had not been performed for one of one persons listed as clinical consultant and two of two technical consultants. (3) The findings were reviewed with testing person #3 who stated on 03/25/2025 at 2:00 pm, competency assessments had not been performed for the roles of clinical consultant and technical consultant.
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 records, policies and procedures and interview with the laboratory manager, the laboratory failed to have written policy defining the method to verify the accuracy of the urine drug screen testing at least twice annually during a review period of 06/01/2023 through 12/31/2024. Findings include: (1) On 03/27 /2025 at 01:30 pm, the technical consultant stated the Alere multi-CLIN drug screen test devices had been put into use for patient testing on 04/01/2023 (refer to D5423 for specific information pertaining to the test kit not being FDA approved and defaulting to a high complexity test system); (2) A review of urine drug screen records, policies and procedures, and proficiency testing for 2024 revealed the laboratory had not enrolled and participated in a proficiency testing program and there was no evidence a policy had been written to ensure a method to verify the accuracy of the testing at least twice annually; (3) The records were reviewed with the laboratory manager who stated on 03/27/2025 at 01:30 pm the laboratory did not have a method to verify the accuracy of urine drug screen testing at least twice annually because it was believed the test kit was categorized as waived; (4) Refer to D5423 for examples of patient testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the interim laboratory manager, the laboratory failed to ensure one of one box of QIAstat RP SARS-Co-V-2 Control materials was stored as required by the manufacturer for two of 25 days reviewed. Findings include: (1) On 03/25/2025 at 02:00 pm, observation of the contents of the chemistry freezer identified the following: (a) One box of QIAstat RP SARS-Co-V-2 Control materials, lot # M22NOV24. (2) The storage requirement, as stated on the box for the control materials was -15 degrees C (Celsius) to -25 degrees C; (3) Observation of the freezer temperature on 03/25/2025 at 2:00 pm identified the current temperature reading as -27 degrees C; (4) A review of the freezer temperature logs from March 1 to March 25, 2024 identified the following: (a) The temperatures were colder than -25 degrees C for two of 25 days reviewed. (5) The findings were reviewed with the technical consultant who stated on 03/25/2025 at 2:00 pm, the freezer temperatures were not within the manufacturer's storage requirements.
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 insert and test kit box, FDA database, email correspondence with FDA representative, and interview with the technical consultant and testing person #3, the laboratory failed to establish the performance specifications for the Alere multi-CLIN Drug Screen Test Device not categorized by the FDA. Findings include: (1) On 03/25/2025 at 11:00 am, the technical consultant stated urine drug screen testing was performed using the Alere multi-CLIN Drug Screen Test Device test kit, as stated on the test kit box; (2) On 03/25/2025 a review of the urine drug screen package insert showed the name of the manufacturer as "Alcon" which did not match the name on the test kit box; (3) 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 03/26/2025; (4) Interview with testing person #3 on 03/27/2025 at 01:00 pm confirmed the test kit had been put into use for patient testing on or around 06/1/2024; (5) 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; (6) The findings were reviewed with the technical consultant, who stated on 03/27/2025 at 01:00 pm 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; (7) The following were examples of patient urine drug screen testing performed (number represents accession number): (a) Patient #903241790005 - Testing performed on 06 /27/2024 (b) Patient #903242010013 - Testing performed on 07/19/2024 (c) Patient #903242180027 - Testing performed on 08/05/2024 (d) Patient #903242480001 - Testing performed on 09/04/2024 (e) Patient #903242720001 - Testing performed on 09/28/2024 (f) Patient #903242800001 - Testing performed on 10/06/2024 (g) Patient #903242820022 - Testing performed on 10/08/2024 (h) Patient #903242950013 - Testing performed on 10/21/2024 (i) Patient #903243130002 - Testing performed on 11/08/2024 (j) Patient #903243190005 - Testing performed on 11/14/2024 (k) Patient #903243310041 - Testing performed on 11/26/2024 (l) Patient #903243590012 - Testing performed on 12/25/2024 (m) Patient #903243610002 - Testing performed on 12/26/2024 (n) Patient #903243610002 - Testing performed on 12/26/2024
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, manufacturer's maintenance checklist, and interview with technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures during the review period of July 2023 through the current date. Findings include: (1) On 03/26/2025 at 11:15 am, the technical consultant stated Protime and Activated Partial Prothrombin Time testing were performed using the Sysmex CA-600 series analyzer; (2) A review of the the manufacturer's CA-600 maintenance Checklist required the following maintenance procedure: (a) Yearly - "Replace Rinse Filter". (3) A review of maintenance logs from July 2023 through the current date identified the yearly maintenance had not been documented as performed between 07/01/2023 and 03/26 /2025; (4) The findings were reviewed with the technical consultant who stated on 03 /26/2025 at 11:15 am the laboratory was unable to provide documentation of maintenance performed 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 technical consultant and testing person #3, the laboratory failed to perform a negative and positive control material 14 of 14 days of patient urine drug screen testing. Findings include: (1) On 03/27/2025 at 01:35 pm, testing person #3 stated the Alere multi-CLIN Drug Screen Test Device had been put into use for patient testing on or around 06/01/2024 (refer to D5423 for

	specific information pertaining to the test kit not being FDA approved and defaulting to a high complexity test system); (2) A review of QC (Quality Control) and patient testing records from June 2024 through December 2024, revealed negative and positive QC materials had not been performed each day of patient testing for 14 of 14 days of patient testing and there was no evidence an IQCP (Individualized Quality Control Program) had been developed; (3) The technical consultant stated on 03/27 /2025 at 01:35 pm negative and positive QC materials had not been performed each day of patient testing and an IQCP had not been developed because it was believed the test kit was categorized as waived; (4) The following were the days of patient testing reviewed when negative and positive QC materials had not been performed: (a) Patient #903241790005 - Testing performed on 06/27/2024 (b) Patient #903242010013 - Testing performed on 07/19/2024 (c) Patient #903242180027 - Testing performed on 08/05/2024 (d) Patient #903242480001 - Testing performed on 09/04/2024 (e) Patient #903242720001 - Testing performed on 09/28/2024 (f) Patient #903242800001 - Testing performed on 10/06/2024 (g) Patient #903242820022 - Testing performed on 10/08/2024 (h) Patient #903242950013 - Testing performed on 10/21/2024 (i) Patient #903243130002 - Testing performed on 11/08/2024 (j) Patient #903243190005 - Testing performed on 11/14/2024 (k) Patient #903243310041 - Testing performed on 11/26/2024 (l) Patient #903243590012 - Testing performed on 12/25/2024 (m) Patient #903243610002 - Testing performed on 12/26/2024 (n) Patient #903243610002 - Testing performed on 12/26/2024
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). 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 one emergency releases reviewed. Findings include: (1) On 03 /27/2025 at 10:00 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 03/27/2025 a review of the form titled, "Release of uncrossmatched blood" required a Release of Uncrossmatched form be completed and stated, "Due to life-threatening condition of this patient: I hereby authorize the administration of unit #_____ to patient_____ on _____ with the knowledge that this is an uncrossmatched unit which could result in complications of a transfusion reaction. The form included a space for the attending physician signature"; (3) A review of documentation of emergency issue identified the following for one of one patient records: (a) One unit of O negative packed red blood cells had been released to a patient on 04/21/2024. The "Release of Uncrossmatched Blood" 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 03/27/2025 at 10:00 am, the emergency release had not been signed by a physician.
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 technical consultant, 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 three of nine Immunohematology, Hematology/Coagulation and Chemistry core proficiency testing events reviewed in 2024. Findings include: (1) A review of 2024 proficiency testing events identified attestation statements had been signed after the samples had been tested (after the graded evaluations were available from the proficiency testing program) for three of nine events reviewed: (a) First Hematology/Coagulation Event - The sample testing had been completed on 03/12 /2024 and the attestation statement had not been signed by the laboratory director until 05/21/2024; (b) First Immunohematology Event - The sample testing had been completed on 04/02/2024 and the attestation statement had not been signed by the laboratory director until 05/21/2024; (c) Third Chemistry Core Event - The sample testing had been completed on 08/28/2024 and the attestation statement had not been signed by the laboratory director until 10/28/2024; (2) The records were reviewed with the technical consultant who stated on 03/25/2025 at 1:45 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 insert and test kit box, FDA database, email correspondence with an FDA representative, and interview with the technical consultant and laboratory manager, the laboratory director failed to provide overall management and direction for a urine drug screen test for nine of nine months of testing. Findings include: (1) The laboratory director failed to ensure the multi-CLIN Drug Screen Test Device urine drug screen test provided quality results for patient care for nine of nine 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 insert and test kit box, FDA database, email correspondence with FDA representative, and interview with the technical consultant and testing person #3, the laboratory director failed to ensure a urine drug screen test provided quality results for patient care for nine of nine months of patient testing. Findings include: (1) The laboratory director failed to ensure the

	FDA categorization of the Multi-CLIN Drug Screen Test Device prior to using for patient testing. Refer to D5401, D5423, and D5449.