Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472771	03/31/2023
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 03/31/2023. The laboratory was found out of compliance with the following CLIA Condition: 493.1409; D6033: Technical Consultant The findings were reviewed with the chief executive officer and interim laboratory manager during an exit conference performed at the conclusion of the survey.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of policies and interview with testing person #1, the laboratory failed to ensure one of three policies had been approved, signed, and dated by the current laboratory director. Findings include: (1) On 09/30/2022 at 02:50 pm, testing person #1 stated the Respiratory SARS-CoV-2 Panel Cartridge was performed using the Qiagen QIA Stat DX analyzer and an IQCP (Individualized Quality Control Plan) had been developed for the test system: (2) A review of the IQCP identified the QCP (Quality Control Plan) for the test system had not been approved, signed, and dated by the laboratory director; (3) The records were reviewed with testing person #1 who stated on 03/30/2023 at 02:06 pm, the QCP for the above test system had not been approved, signed, and dated by the laboratory director.
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 testing person #1, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for two of four analyzers. Findings include: SYSMEX CA-660 (1) On 03/27/2023 at 02:57 pm, testing person #1 stated the laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing using the Sysmex CA-660 analyzer; (2) A review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Quarterly - "Clean DI Water Rinse Bottle with Alcohol" (b) Yearly - "Replace Rinse filter" (3) A review of maintenance logs from 01/01/2022 through 02/28/2023 identified maintenance had not been performed as follows: (a) Quarterly - Not documented as performed after 04/08/2022 (b) Yearly - Not documented as performed during the review period (4) The records were reviewed with testing person #1 who stated on 03/30/2023 at 01:15 pm the maintenance had not been documented as performed as shown above. QIAGEN STAT DX (1) On 03/27 /2023 at 03:00 pm, testing person #1 stated the laboratory performed testing for Adenovirus, Coronavirus 229E, Coronovirus HRU1, Coronovirus ML63, Coronovirus OC43, Human Metapnuemonovirus, Influenza A, Influenza AH1, Influenza AH1N1, Influenza H3, Infuenza B, Parainfluenza Virus 1, 2, 3 4, RSV A&B, Rhinovirus /Enterovirus, SARS-CoV2, Bordetella Pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae were performed using the Respiratory SARS-CoV-2 Panel Cartridge and the Qiagen QIA Stat DX analyzer; (2) A review of the operator's manual in section 8 "Maintenance" stated "The air filter must be changed every year to ensure the appropriate airflow rate inside the unit"; (3) A review of records from June 2021 through February 2023 identified no evidence the air filter had been changed during the review period; (4) The findings were reviewed with testing person #1 who stated on 03/30/2023 at 03:46 pm, the maintenance had not been documented as performed.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (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 and interview with the interim laboratory manager, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly during the review period of June 2021 through the current date. Finding include: (1) On 03/29/2023 at 02:50 pm, the laboratory manager stated the following: (a) Urine sediment examinations were performed in the laboratory; (b) The specimens were processed in the Labsco Model 614V centrifuge at a speed of 1800 rpm (revolutions per minute) for 5 minutes; (2) A review of the policy titled, "Urinalysis Centrifuge RPM and Timer Check" stated the following: (a) "The time of

	the centrifugation of the Labsco 614V centrifuge used for urinalysis must be verified once every six months and documented on the Verification and Maintenance Log Sheet"; (b) "The RPM of the Labsco 614V Centrifuge used for urinalysis must be verified once every six months and documented on the Verification and Maintenance Log Sheet". (3) A review of centrifuge records from June 2021 through the current date identified the centrifuge speed and timer had not been checked between 01/12 /2022 and 01/31/2023; (4) The records were reviewed with the interim laboratory manager who stated on 03/30/2023 at 10:15 am the laboratory had not followed their policy.
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 interim laboratory manager and testing person #1, the laboratory failed to perform calibration verification procedures at least once every six months for three of three test systems. Findings include: EPOC (1) On 03/29/2023 at 02:18 pm, the interim laboratory manager stated the laboratory performed BUN, Chloride, Creatinine, CO2, Glucose, Sodium, and Potassium testing using the EPOC analyzer as a backup method to the Ortho Vitros 350 analyzer; (2) On 03/30/2023 a review of records from January 2022 through the current date identified no evidence calibration verification had been performed prior to 09/27/2022; (3) The records were reviewed with testing person #1 who stated on 03/30/2023 at 11:05 am, calibration verification procedures had not been performed every six months. TRIAGE METER PRO (1) On 03/29/2023 at 02:25 pm, the interim laboratory manager stated the laboratory performed D-dimer testing using the Biosite Triage Meter Pro analyzer; (2) On 03/30/2023 a review of records from September 2021 through the current date identified no evidence calibration verification had been performed after 02/23/2022; (3) The records were reviewed with testing person #1 who stated on 03/30/2023 at 11:14 am, calibration verification procedures had not been performed every six months. AFFINION 2 (1) On 03/29/2023 at 02:35 pm, the interim laboratory manager stated the laboratory performed Diagnostic Hemoglobin

	A1c testing using the Affinion Hemoglobin A1c DX and the Affinion 2 analyzer; (2) On 03/30/2023 a review of records from June 2021 through the current date identified no evidence calibration verification had been performed as follows: (a) Between 06/14 /2021 and 07/20/2022 (b) After 07/20/2022 (3) The records were reviewed with testing person #1 who stated on 03/30/2023 at 11:40 am, calibration verification procedures had not been performed every six months.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to perform quality control as stated in the IQCP (Individualized Quality Control Plan) for one of three test systems during the review period of September 2022 through February 2023. Findings include: (1) On 03/30/2022 at 02:50 pm, testing person #1 stated the following: (a) Adenovirus, Coronavirus 229E, Coronovirus HRU1, Coronovirus ML63, Coronovirus OC43, Human Metapnuemonovirus, Influenza A, Influenza AH1, Influenza AH1N1, Influenza H3, Infuenza B, Parainfluenza Virus 1, 2, 3 4, RSV A&B, Rhinovirus/Enterovirus, SARS-CoV2, Bordetella Pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae were performed using the Respiratory SARS-CoV-2 Panel Cartridge and the Qiagen QIA Stat DX analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) A review of the QCP (Quality Control Plan) identified positive and negative quality control materials were to be tested each seven days and with new lot numbers of cartridges; (3) A review of QC records from September 2022 through February 2023 identified QC testing had not been performed as stated in the QCP as follows: (a) Between 09/28/2022 and 10/21/2022 (b) Between 10/21/2022 and 11/16/2022 (c) Between 01/13/2023 and 01/27/2023 (d) Between 02 /10/2023 and 02/27/2023 (4) The records were reviewed with testing person #1 who stated on 03/30/2023 at 02:35 pm, QC had not been performed as stated above.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the interim laboratory manager and testing person #1, the laboratory failed to follow the

	manufacturer's specifications for the Architect BNP Controls for one of two months reviewed. Findings include: (1) On 03/31/2023 at 09:05 am, testing person #1 stated the following: (a) BNP (B-Type Natriuretic Peptide) testing was performed using the Abbott Architect Plus i1000 SR analyzer; (b) Three levels of Architect BNP Controls were performed each day of patient testing. (2) A review of the manufacturer;s instructions (package insert) for the control materials stated, "Each laboratory should establish its own concentration ranges for new control lots at each control level"; (3) A review of QC (quality control) records for one lot number of control materials used during the review period of 12/01/2022 through 01/31/2023 identified the following: (a) Control L, Control M, and Control H lot #44K18621 were in use; (b) The laboratory had used the following manufacturer's guideline ranges from 01/01/2023-01 /31/2023 instead of their established ranges: (i) Control L - 57.6-122.4 pg/ml (ii) Control M - 320-680 pg/ml (iii) Control H - 2240-4760 pg/ml (4) The records were reviewed with the interim laboratory manager and testing person #1. Both stated on 03 /31/2023 at 10:50 am the laboratory had not followed the manufacturer's instructions for the control materials.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) 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 testing person #1, the laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing for one of 21 patients reviewed. Findings include: (1) On 03/30 /2023 at 02:40 pm, testing person #1 stated the following: (a) Blood gas testing (pH, pCO2, pO2) was performed on the EPOC analyzer; (b) Two levels of quality control (QC) material were performed each eight hours of patient testing. (2) A review of QC and patient records for testing performed from 06/06/2022-01/16/2023 identified that QC testing had not been performed each eight hours of patient testing (two levels had not been performed on the day of patient testing) for one of 21 patients reviewed: (a) The patient had been tested on 06/30/2022; (b) Two levels of QC materials had not been tested between 06/27/2022 and 07/01/2022. (3) The records were reviewed with testing person #1 who stated on 03/30/2023 at 03:35 pm, QC testing had not been performed each eight hours of patient testing.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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, policies and procedures, and interview with the interim laboratory manager, the laboratory failed to ensure units of blood were stored under appropriate conditions during the review period of June 2021 through December 2022. Findings include: (1) On 03/29/2023 at 02:20 pm, the interim laboratory manager stated the laboratory stored units of packed red blood cells in the Helmer blood bank refrigerator. The units were to be used for patient transfusions; (2) A review of the policy titled "Blood Bank Alarm Test" stated, "The alarm system should be tested quarterly"; (3) A review of alarm check records from June 2021 through December 2022 identified no evidence the alarm checks had been performed between: (a) 09/17/2021 and 03/30/2022 (b) 03/20/2022 and 03/21/2023 (4) The findings were reviewed with the interim laboratory manger who stated on 03/30/2023 at 09:50 am there was no documentation to prove the alarm checks had been performed as stated above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the interim laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for Routine Chemistry testing performed using two test methods during the review period of June 2021 through January 2023. Findings include: (1) On 03/29/2023 at 02:18 pm, the interim laboratory manager stated the laboratory performed BUN, Chloride, Creatinine, CO2, Glucose, Sodium, and Potassium testing using the EPOC analyzer as a backup method to the Ortho Vitros 350 analyzer; (2) On 03/30/2023 a review of records from January 2022 through the current date identified the relationship between the two test methods had not been evaluated after 06/07/2022; (3) The records were reviewed with testing person #1 who stated on 03/30/2023 at 11:10 am, the relationship between the above test methods had not been evaluated at least twice annually during the review period.
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 testing person #1, the laboratory failed to follow their policy for monitoring the effectiveness of their QCP (Quality Control Plan) for one of three test systems. Findings include: (1) On 03/30/2022 at 02: 50 pm, testing person #1 stated the following: (a) Adenovirus, Coronavirus 229E,

	Coronovirus HRU1, Coronovirus ML63, Coronovirus OC43, Human Metapnuemonovirus, Influenza A, Influenza AH1, Influenza AH1N1, Influenza H3, Infuenza B, Parainfluenza Virus 1, 2, 3 4, RSV A&B, Rhinovirus/Enterovirus, SARS-CoV2, Bordetella Pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae were performed using the Respiratory SARS-CoV-2 Panel Cartridge and the Qiagen QIA Stat DX analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system, dated as approved on 02/21/2021. (2) A review of the IQCP identified that QA (Quality Assessment) reviews of the QCP (Quality Control Plans) were to be performed on an annual basis; (3) A review of records for the test system from 2021 through the current date identified no documentation an annual QA review had been performed since the implementation of the test system; (4) The records were reviewed with testing person #1 who stated on 03 /30/2023 at 02:32 pm, an annual QA review had not been documented as performed since the implementation of the IQCP.
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 one patient report and interview with the interim laboratory manager and testing person #1, the laboratory failed to make appropriate reference ranges available for two of two reagent lot numbers implemented for PT (Prothrombin Time) and PTT (Partial Thromboplastin Time) testing. Findings include: (1) On 03/29 /2023 at 02:57 pm, the interim laboratory manager stated the laboratory performed PT /INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing using the Sysmex CA-660 analyzer; (2) On 03/30/2023 at 11:30 am, testing person #1 stated the following reagent lot numbers were put into use on 10/04/2022: (a) Dade Innovin lot #564616A (b) Dade Actin FSL - #562705 (3) A review of the implementation records identified the following: (a) PT - The normal reference interval had been verified as 9.7-10.9 (b) PTT - The normal reference interval had been verified as 23.8-25.3 (4) A review of a patient report with PT and PTT testing performed on 03/16/2023 showed the following normal ranges: (a) PT - 9.0-11.0 (b) PTT - 21.1-27.7 (5) The reports and implementation records were reviewed with testing person #1 who stated on 03/30/2023 at 01:30 pm, the laboratory had not updated the normal reference ranges into the laboratory's computer information system.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the interim laboratory manager, the technical consultant failed to provide technical supervision in accordance with

	493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035; (2) 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 three testing persons. Refer to D6053.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the interim laboratory manager, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for three of four competency evaluations. Findings include: (1) On 03/29/2023 a review of records for four persons performing moderate complexity testing during 2021 and to date in 2023 identified the following for three of four testing persons: (a) Testing Person #1 - The 08/17/2022 evaluation had been performed by an individual who did not meet the regulatory requirements of a technical consultant; (b) Testing Person #3 - The 08/17 /2023 evaluation had been performed by an individual who did not meet the

	regulatory requirements of a technical consultant; (c) Testing Person #4 - The 08/19 /2022 evaluation had been performed by an individual who did not meet the regulatory requirements of a technical consultant. (2) The records were reviewed with the interim manager who stated on 03/27/2023 at 04:00 pm, the evaluations had been performed by an individual who did not meet the qualifications of a technical consultant.
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 interim 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 three testing persons. Findings include: (1) On 03/29/2023 a review of personnel records for three persons hired to perform moderate complexity testing after the previous recertification survey identified the following for one of three persons: (a) Testing Person #4 - The initial training was complete on 06/21/2021. There was no evidence a competency evaluation had been performed prior to 08/19/2022; (2) The records were reviewed with the interim laboratory manager who stated on 03/29/2023 at 04:17 pm, a semiannual competency evaluation had not been performed.