Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0050739	03/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Beaver County Hospital Authority	212 East 8th Street, Beaver, 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 03/27,28,29/2023, The laboratory was found out of compliance with the following CLIA Conditions: 493.1409; D6033: Technical Consultant The findings were reviewed with the hospital administrator, interim laboratory manager, and testing person #2 at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the interim laboratory manager, the testing person(s) failed to sign a proficiency testing attestation statement for one of three chemistry core proficiency testing events reviewed in 2022. Findings include: (1) On 03/27/2023 a review of chemistry core proficiency testing records for 2022 identified the following for one of three events: (a) Third 2022 Event - The attestation statement had not been signed by the testing person(s). (2) The findings were reviewed with the interim laboratory manager who stated on 03/27/2023 03:09 pm the attestation statement had not been signed by the testing person(s).
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 interim laboratory manager and testing person #2, the laboratory failed to provide written instructions to clients collecting and referring routine Hematology, Chemistry and Urinalysis testing. Findings include: (1) On 03/27 /2023 at 02:47 pm, the laboratory manager stated the following: (a) Routine Chemistry testing was performed using the Ortho Vitros 350 analyzer; (b) Routine CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer; (c) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Sysmex CA-660 analyzer; (d) The laboratory performed urine sediment examinations; (e) Specimens were transported to the laboratory from a local long term care facility. (2) Interview with the interim laboratory manager and testing person #2 on 3/29/23 at 11:30 am confirmed the laboratory did provide written instructions (i.e.,client service manual) to the client to explain the laboratory's specimen handling policies.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. 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 #2, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents for two of two lot numbers. Findings include: (1) On 03/28/2023 at 11:00 am, the interim laboratory manager stated: (a) The laboratory began using the Sysmex CA-660 analyzer to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing for adults on 04/18/2022; (b) The following reagent lot numbers were put into use on 04/18/2022: (i) PT - Innovin reagent, lot #564605 (ii) PTT - Actin FSL reagent, lot #562683 (2) A review of the manufacturer's instructions contained in the "Sysmex Installation Package" for establishing the reference intervals stated: (a) "Donors must be from a health population"; (b) "Donors should span the age range of the population being tested"; (3) A review of the implementation records for the PT and PTT reagents identified the following: (a) PT Innovin Reagent (i) Although the laboratory had tested 22 samples (11 males and 11 females), there was no documentation of the medication history and health status to ensure the donors were from a healthy population; (ii) There was no documentation of the age of the donors to ensure they spanned the adult age range. (b) PTT Actin FSL Reagent (i) Although the laboratory had tested 22 samples (11 males and 11 females), there was no documentation of the medication history and health status to ensure the donors were from a healthy population; (ii) There was no documentation of the age of the donors to ensure they spanned the adult age range. (4) The records were reviewed

	with testing person #2 who stated on 03/28/2023 at 01:20 pm, the laboratory had not followed the manufacturer's instructions for the implementing the reagents as shown above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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, manufacturer's instructions, and interview with the interim laboratory manager, the laboratory failed to ensure the humidity was maintained as required by the manufacturer of the Sysmex XS-1000i and Sysmex CA-660 analyzers for nine of 13 months reviewed. Findings include: (1) On 03/27/2023 at 02:50 pm, the interim laboratory manager stated CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer; (2) On 03/28/2023 at 11:00 am, the interim laboratory manager stated the laboratory began using the Sysmex CA660 analyzer to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing for adults on 04/18/2022; (3) On 03/29 /2023 review of the manuals for the test systems identified the following: (a) Sysmex XS-1000i - The manual titled, "Instructions for Use" in Section 11.11 "Installation Environment" stated "Relative humidity should be in the range of 30-85%"; (b) Sysmex CA600 - The manual titled, "Instructions for Use" in Section 4.2 "Installation Environment" stated "Use the instrument at a relative humidity range of 30-85%". (4) A review of the laboratory humidity records from February 2022 through February 2023 identified the humidity readings were less than 30% for nine of 13 months as follows: (a) February 2022 - 28 of 28 humidity readings were documented as less than 30%; (b) March 2022 - 30 of 31 humidity readings was documented as less than 30%; (c) April 2022 - 20 of 30 humidity readings was documented as less than 30%; (d) May 2022 - One of 31 humidity readings was documented as less than 30%; (e) October 2022 - Ten of 31 humidity readings was documented as less than 30%; (f) November 2022 - 23 of 30 humidity readings was documented as less than 30%; (g) December 2022 - 31 of 31 humidity readings was documented as less than 30%; (h) January 2023 - 31 of 31 humidity readings was documented as less than 30%; (i) February 2023 - 28 of 28 humidity readings was documented as less than 30%. (4) The records were reviewed with the interim laboratory manager who stated on 03/29 /2023 at 09:45 am the laboratory humidity had not been maintained as required by the manufacturer as shown above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the interim laboratory manager and testing person #2, the laboratory failed to utilize the demonstrated reportable range for one of two new test methods; and failed to ensure the performance specification data had been evaluated prior to implementing the new testing for one of two new test methods introduced into the laboratory. Findings include: MINII SED ANALYZER (1) On 03/28/2023 at 10:30 am, testing person #2 stated the laboratory obtained a replacement miniiSED analyzer and began using it for patient testing on 08/20/2022; (2) A review of the performance specification records for the analyzer identified the laboratory had demonstrated a reportable range of 2-77 mm/hr; (3) Interview with testing person #2 on 03/28/2023 at 11:20 am confirmed the laboratory was using the reportable range of 4-99 mm/hr, which had been demonstrated with the previous analyzer instead of the reportable range that had been demonstrated by the laboratory for the replacement analyzer. SYSMEX CA-660 (1) On 03/27/2023 at 02:40 pm, the interim laboratory manager stated the laboratory began using the Sysmex CA-660 analyzer to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing on 04/18/2022; (2) A review of the performance specification records for the new test system identified no evidence the data had been signed and dated as approved by the laboratory prior to putting into use for patient testing; (3) Interview with the interim laboratory manager on 03/28/2023 at 02:55 pm confirmed there was no documentation to prove the performance specification data had been reviewed and approved by the laboratory prior to putting into use.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the interim laboratory manager and testing person #2, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for three of three analyzers reviewed from 05/01/2022 through 02/28/2023. Findings include: SYSMEX XS-1000i (1) On 03/27/2023 at 02:50 pm, the interim laboratory manager stated CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer; (2) On 03/28/2022, a review of the manufacturer's maintenance log showed the following required weekly maintenance procedure: (a) "Power Down IPU" (3) A review of maintenance logs from 05/01/2022 through 02/28 /2023 identified weekly maintenance had not been documented as performed between: (a) 05/20/2022 and 06/02/2022 (b) 09/23/2022 and 10/07/2022 (c) 10/21/2022 and 11 /04/2022 (d) 01/06/2023 and 01/20/2023 (4) The records were reviewed with the interim laboratory manager and testing person #2. Both stated on who stated on 03/28 /2023 at 03:15 pm the weekly maintenance had not been documented as performed as shown above. SYSMEX CA-660 (1) On 03/28/2023 at 11:00 am, the interim

	laboratory manager stated: (a) The laboratory began using the Sysmex CA-660 analyzer to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing for adults on 04/18/2022; (2) A review of the manufacturer's maintenance log showed the following required weekly maintenance procedure: (a) "Clean Instrument Interior/Exterior" (3) A review of maintenance logs from 05/01/2022 through 02/28/2023 identified weekly maintenance had not been documented as performed between: (a) 09/23/2022 and 10/07/2022 (b) 12/23/2022 - 01/06/2023 (4) The records were reviewed with testing person #2 who stated on 03/28/2023 at 11:55 am the weekly maintenance had not been documented as performed as shown above. ORTHO VITROS 350 (1) On 03/28/2023 at 01:05 pm, the interim laboratory manager stated the laboratory performed Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Amylase, Direct Bilirubin, Ethanol, Total Bilirubin, BUN, Calcium, Chloride, Total Cholesterol, CO2, CK (Creatine Kinase), Creatinine, Glucose, HDL Cholesterol, Lactic Acid, Lipase, magnesium, Phosphorus, Total Protein, Sodium, Triglyceride, Acetaminophen, Digoxin, Salicylate, and Uric Acid testing using the Ortho Vitros 350 analyzer; (2) A review of the manufacturer's maintenance log showed the following required weekly maintenance procedures: (a) Clean Tray Platform and Transport Arm (b) Clean Cup Retainer (c) Clean Diluent Bottles (d) Clean Tip Locator Assembly (e) Clean Control Unit Screen (f) Clean Keypad Cover (g) Inspect, Clean, and/or Replace Air Filter (h) Back up QC/Config/Calibration Data (3) A review of maintenance logs from 05/01/2022 through 02/28/2023 identified the weekly maintenance procedures had not been documented as performed as follows: (a) Although checkmarks had been documented on the maintenance log to indicate the weekly maintenance had been performed, there were no dates to prove when it had been performed, therefore, it could not be determined if the procedures had been performed on a weekly basis between 06/24/2022 and 09/02/2022; (b) Although checkmarks had been documented on the maintenance log to indicate the weekly maintenance had been performed, there were no dates to prove when it had been performed, therefore, it could not be determined if the procedures had been performed on a weekly basis between 10/21 /2022 through the end of the review period. (4) The records were reviewed with the interim laboratory manager and testing person #2. Both stated on 03/28/2023 at 03:50 pm there were no records to prove the weekly maintenance had been performed as shown above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable

	limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the interim laboratory manager and testing person #2, the laboratory failed to perform calibration verification procedures at least once every six months for one of two test systems. Findings include: (1) On 03/27/2023 at 02:15 pm, the interim laboratory manager stated the laboratory performed D-dimer testing using the Biosite Triage Meter Pro analyzer; (2) On 03/28/2023 a review of records from August 2021 through the current date identified no evidence calibration verification had been performed at least once every six months during the review period; (3) The records were reviewed with testing person #2 who stated on 03/28/2023 at 10:00 am, calibration verification procedures had not been performed every six months.
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 #2, 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 03/28/2023 at 11:00 am, the interim laboratory manager stated: (a) The laboratory began using the Sysmex CA-660 analyzer to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing for adults on 04/18/2022; (b) The following reagent lot numbers were put into use on 04/18/2022: (i) PT - Innovin reagent, lot #564605 (ii) PTT - Actin FSL reagent, lot #562683 (2) A review of the implementation records identified the following: (a) PT - The normal reference interval had been verified as 9.40-11.50 (b) PTT - The normal reference interval had been verified as 23.5-31.3 (3) A review of a patient report with PT and PTT testing performed on 02/21/2023 at 11:18 am showed the following normal ranges: (a) PT - 10.8-14.0 (b) PTT - 19.0-34.0 (4) The reports and implementation records were reviewed with the interim laboratory manager and testing person #2. Both stated on 03/29/2023 at 10:20 am, 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 personnel performing moderate complexity testing had been evaluated at least annually for one of four persons. Refer to D6054.
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 two of four competency evaluations and one of three chemistry core proficiency testing attestation forms. Findings include: COMPETENCY EVALUATIONS (1) On 03/27/2023 a review of records for four persons performing moderate complexity testing during

	2021 and to date in 2023 identified the following for two of four testing persons: (a) Testing Person #3 - The 08/11/2022 evaluation had been performed by an individual who did not meet the regulatory requirements of a technical consultant; (b) Testing Person #5 - The 03/06/2023 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 02:04 pm, the evaluations had been performed by an individual who did not meet the qualifications of a technical consultant. PROFICIENCY TESTING ATTESTATIONS (1) On 03/27 /2023 a review of 2022 chemistry core proficiency testing records identified one of three attestation statements (third 2022 event) had been signed by an individual who did not meet the minimal educational qualifications of a technical consultant or designee; (2) The records were reviewed with the interim laboratory manager who stated on 03/27/2023 at 03:09 pm, the attestation statement had been signed and dated by an individual who did not meet the regulatory qualification requirements of a technical consultant or designee.
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 interim laboratory manager, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for one of four persons. Findings include: (1) On 03/27/2023 a review of personnel records for four persons performing moderate complexity testing during 2020 and to date in 2023 identified no evidence an annual competency evaluation had been performed for one of four testing persons as follows: (a) Testing Person #3 - Between 09/30/2020 and 06/29/2022 (2) The records were reviewed with the interim manager who stated on 03/27/2023 at 02:04 pm, the annual evaluation had not been performed.