Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0050739	01/16/2019
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 01/14/19 through 01/16/19. The findings were reviewed with the laboratory director, laboratory supervisor, and hospital administrator during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
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 laboratory supervisor, the laboratory failed to follow their written general supervisor competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) On the second day of the survey, the surveyor reviewed the policy titled, "Reapportion of Laboratory Director responsibilities to Other Personnel" which stated, "The Laboratory Director will evaluate and document competency of the General Supervisor at least once annually"; (2) The surveyor then reviewed personnel records for competency assessments performed during 2017 and 2018. There was no evidence the general supervisor competencies, based on their job responsibilities, had been performed; (3) The surveyor asked the laboratory supervisor if there was documentation to substantiate competencies had been performed for the general supervisor based on job responsibilities in 2017 and 2018. The laboratory supervisor stated the general supervisor competencies, based on job responsibilities, had not been performed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed the 2017 and 2018 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2018 Hematology Event (i) Platelet - 3 of 5 results exhibited a positive bias (aa) Sample XE-02 - SDI of 3.0 (bb) Sample XE-03 - SDI of 2.5 (cc) Sample XE-04 - SDI of 3.3 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory supervisor who stated the biases had not been addressed. NOTE: D5211 was cited on the recertification survey performed on 05/10,11,12/17.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to evaluate the accuracy of testing when a proficiency result had not been graded by the proficiency program. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Chemistry Core (i) 2017 third event (aa) CK-MB sample CH-15 (ii) 2018 third event (aa) CK-MB samples CH-11, CH-12, CH-13, CH-14 and CH-15 (b) Hematology /Coagulation (i) 2018 first event (aa) BCI (Blood Cell Identification) sample BCI-01 (bb) PT (Prothrombine Time) sample HCP-05 (cc) PTT (Partial Thromboplastin Time) sample HCA-03 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyor asked the laboratory supervisor if the results had been documented as evaluated. The laboratory supervisor reviewed the records and stated the non-graded results had not been documented as reviewed. NOTE: D5215 was cited on the recertification survey performed on 05/10,11,12/17
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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, written policy, and interview with the laboratory supervisor, the laboratory failed to follow their written policy for emergency issue of blood. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor ABO/Rh, Antibody Screen, and Compatibility testing were performed using the tube method; (2) The surveyor reviewed the policy titled "EMERGENCY ISSUE OF BLOOD FOR TRANSFUSION", which stated, "Routine compatibility testing will be completed promptly. If incompatibility is found, the physician will be alerted immediately by the Blood Bank technician"; (3) The surveyor then reviewed 2018 emergency issue of blood for transfusion and identified the following: (a) Routine compatibility testing had not been documented as performed for the following: (i) O Negative unit (W200218573396) issued on 12/16 /18; (4) The surveyor reviewed the findings with the laboratory supervisor, who stated compatibility testing had not been performed for the unit as required by policy. NOTE: 5401 was cited on the recertification survey performed on 05/10,11,12/17
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 laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor routine chemistry testing was performed on the Ortho Vitros 350 analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements, as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were as follows: (a) Clean tray platform and transport arm (b) Clean cup retainer (c) Clean diluent bottles (d) Clean tip locator assembly (d) Clean control unit screen (e) Clean keypad cover (f) Inspect, clean and/or replace air filter (3) The surveyor then reviewed maintenance records between January 2018 through the second day of the survey. The following was identified: (a) There was no evidence the weekly maintenance had been performed: (i) Between 12/14/18 and 01/14/19 (4) The surveyor reviewed the records with the laboratory supervisor, who stated the maintenance records were not available to demonstrate maintenance had been performed as required. NOTE: D5429 was cited on the recertification survey performed on 05/10,11,12/17
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, policies and procedures, and interview with the laboratory supervisor, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor urine sediment examinations were performed in the laboratory. The specimens were processed in the Damon IEC Sorvall Easyspin centrifuge at a speed of 1800 rpm (revolutions per minute) for 5 minutes; (2) The surveyor reviewed the policy titled "CENTRIFUGE AND PERFORMANCE CHECKS". It stated "Centrifuges will be checked routinely at least once annually for proper performance. Performance checks shall also be done when the equipment is accidentally dropped, moved to another environment or when test results do not yield expected results."; (3) The surveyor reviewed the centrifuge maintenance records for 2017 and 2018: (a) The speed and time were checked on the following dates: (i) 11/09/17 - 3305 rpm for 5 minutes (ii) 11/28/18 - 3309 rpm for 5 minutes (b) There was no evidence the centrifuge speed had been checked at 1800 rpm (the speed used to process urine specimens) during 2017 and 2018; (4) The surveyor reviewed the findings with the laboratory supervisor, who stated the centrifuge speed had not been checked at the speed used to process urine specimens.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 the laboratory supervisor, the laboratory failed to have control procedures that monitored the accuracy of the analytic process. Findings include: (1) On the third day of the survey, the laboratory supervisor stated the following to the surveyor: (a) CK (Creatine Kinase) testing was performed using the Ortho Vitros 350 analyzer; (b) Two levels of Ortho Vitros control materials were performed each day of patient testing. (2) The surveyor reviewed quality control records for testing performed between 11/25/18 through 01/13/19. The following bias (the control results were consistently below the established mean) were identified as follows: (a) CK level 2 (lot# C6274 - put into use on 10/18/18) - 47 out of 48 control results were below the mean. (3) There was no evidence in the records the control bias had been identified and addressed; (4) The surveyor reviewed the records with the laboratory supervisor and asked if there was documentation to prove the bias had been identified and addressed. The laboratory supervisor stated the bias had not been addressed; (5) Since the above bias had not been identified and

	addressed, the surveyor determined the laboratory failed to have control procedures that monitored the accuracy of testing for the above analyte.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed using the Sysmex 1000i analyzer; (2) On the third day of the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 01/14/19 at 08:29 am; the second report was for an adult male patient with the testing performed on 08/16/18 at 02:05 pm. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit which were: (a) RBC - 3.80 - 5.10 L (b) Hemoglobin - 11.7 - 15.5 gm/dL (c) Hematocrit - 35 - 45 % (3) The surveyor reviewed the findings with the laboratory supervisor, who stated the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, 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. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. It was identified for 5 of 12 events, the attestation statements had been signed approximately 2 - 4 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Third 2017 Hematology/Coagulation Event - The samples had been tested on 11/28/17 and the attestation statement had not been signed by the laboratory director until 01/09/18; (b) First 2018 Chemistry Core Event - The samples had been tested on 02/06/18 and the attestation statement had not been signed by the laboratory director until 04/10/18; (c) Third 2018 Chemistry Core Event - The samples had been tested on 09/13/18 and

	the attestation statement had not been signed by the laboratory director until 01/05/19; (d) Second 2018 Hematology/Coagulation Event - The samples had been tested on 07 /19/18 and the attestation statement had not been signed by the laboratory director until 09/08/18; (e) Third 2018 Hematology/Coagulation Event - The samples had been tested on 11/27/18 and the attestation statement had not been signed by the laboratory director until 01/05/19. (2) The surveyor reviewed the findings with laboratory supervisor and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
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 laboratory supervisor, the technical consultant failed to provide technical oversight 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.
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 laboratory supervisor, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: (1) On the first day of the survey, the surveyor reviewed records for 4 persons performing moderate complexity testing in 2018. The records indicated the evaluations for 4 of 4 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 (i) The 10/25/18 evaluation had been performed by the laboratory supervisor (this person had earned an associate degree in applied science). (b) Testing Person #3 (i) The 09/06/18 evaluation had been performed by the laboratory supervisor. (c) Testing Person #4 (i) The 11/16/18 evaluation had been performed by the laboratory supervisor. (d) Testing Person #5 (i) The 11/16/18 evaluation had been performed by the laboratory supervisor. (2) The surveyor explained to the laboratory supervisor that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).