Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470045	11/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Arbuckle Memorial Hospital	2011 W Broadway Ave, Sulphur, 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 11/07,08,09,10/2022, The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, incoming laboratory director, assistant to the laboratory director, and laboratory manager during an exit conference performed 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 laboratory manager, the laboratory director failed to sign a proficiency testing attestation statement for one of five Immunohematology events. Findings include: (1) On 11/07/2022, a review of the 2021 and 2022 Immunohematology proficiency testing records identified the following for one of five events: (a) First 2022 Immunology/Immunohematology Event - The attestation statement had not been signed by the laboratory director. (2) The findings were reviewed with the laboratory manager who stated on 11/08/2022 at 11:07 am the attestation statement had not been signed by the laboratory director.

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 the laboratory manager, the laboratory failed to ensure one of three policies had been approved, signed, and dated by the current laboratory director. Findings include: (1) On 11/07/2022 at , the laboratory manager stated the following: (a) Neisseria gonorrhoeae and Chlamydia trachomatis testing were performed using the Cepheid Gene Xpert analyzer effective 03/19/2021; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) On 11/08/2022, a review of the IQCP identified the QCP (Quality Control Plan) for the test system had not been approved, signed, and dated by the current laboratory director; (3) The records were reviewed with the laboratory manager who stated on 11/08/2022 at 01:32 pm, the QCP for the above test system had not been approved, signed, and dated by the current 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 the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for one of three analyzers reviewed. Findings include: (1) On 11/07/2022 at 10:40 am, the laboratory manager stated Albumin, Alcohol, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Amylase, AST (Aspartate Aminotransferase), BUN (Blood, Urea, Nitrogen), Calcium, CK (Creatine Kinase), Creatinine, Chloride, CO2, Glucose, Lipase, Magnesium, Myoglobin, Phosphorus, Troponin I, Potassium, Sodium, Total Bilirubin, Total Cholesterol, and Total Protein testing were performed on the Siemens Dimension EXL 200 as the STAT analyzer effective 06/24/2022; (2) On 11/09/2022, a review of the "Siemens Dimension Operator's Guide" Chapter 7 titled, "Maintenance" stated the following maintenance requirements: (a) Weekly (i) Clean HM Wash Probes and R2 Reagent Probes (b) Monthly (i) Clean Clot Check Drain on the IMT Port (ii) Replace IMT Pump Tubing (iii) Clean IMT System (iv) Replace Instrument Air filter (v) Stylette HM Wash Probes (vi) Replace HM Pump Heads on Wash Stations (vii) Clean R2 and R3 Drains (3) A review of maintenance records contained in the SQS (Strategic Quality Support System) identified no documentation of the weekly and monthly maintenance procedures during the review period of July 2022 through October 2022; (4) The findings were reviewed with the laboratory manager who stated on 11/09 /2022 at 02:59 pm that although the maintenance procedures had been performed, the tasks had not been built into SQS for the procedures to be documented as performed.
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 the laboratory manager, the laboratory failed to perform quality control as stated in the IQCP for Neisseria gonorrhoeae and Chlamydia trachomatis testing for four of 18 months reviewed. Findings include: (1) On 11/07/2022 at 10:05 am, the laboratory manager stated the following: (a) Neisseria gonorrhoeae and Chlamydia trachomatis testing were performed using the Cepheid Gene Xpert analyzer beginning 03/19/2021; (b) Positive and negative QC (Quality Control) materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan). (2) On 11/08/2022, a review of QC records from June 2021 through the current date identified no documentation to prove QC had been performed as stated in the QCP (Quality Control Plan) for four of 18 months reviewed. QC had not been performed between: (a) 06/31/2021 and 08/05 /2021 (b) 12/17/2021 and 02/02/2022 (c) 03/21/2022 and 05/20/2022 (d) 05/20/2022 and 07/08/2022 (3) The records were reviewed with the laboratory manager who stated on 11/08/22 at 01:45 pm, QC had not been performed as shown 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 laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for Blood Gas testing performed using two test methods. Findings include: (1) On 11/07/2022 at 10:20 am, the laboratory manager stated Blood Gas (pH, pCO2, pO2) testing was performed using the Nova Stat Profile Prime + analyzer as the primary method and the Opti CCA-TS analyzer as the backup method; (2) On 11/08/2022, a review of records from January 2022 through the current date identified no records to prove the relationship between the different test methods had been evaluated during the review period; (3) Interview with the laboratory manager on 11/08/2022 at 02:15 pm confirmed the relationship between the test methods had not been evaluated.
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 the laboratory manager, the laboratory failed to follow their policy for monitoring the effectiveness of their QCP for two of two test systems. Findings include: (1) On 11/07/2022 at 10:30 am, the laboratory manager stated the following: (a) D-dimer testing was performed using the Alere Triage Meter Pro analyzer; (b) PT/INR(Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Hemochron Signature Elite analyzer; (c) IQCP's (Individualized Quality Control Plans) had been developed for the test systems. (2) On 11/08/2022, a review of the IQCP's 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 systems during 2020 and to date in 2022 revealed the IQCP's had been approved on 12/11/2020. There was no documentation QA reviews had been performed during the review period of January 2021 and to date in 2022; (4) The records were reviewed with the laboratory manager who stated on 11/08/2022 at 01: 29 pm, annual QA reviews had not been documented as performed.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high 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 laboratory manager, the technical supervisor failed to ensure that persons performing high complexity testing had been evaluated semiannually during the first year of testing for two of two testing persons. Findings include: (1) On 11/07/2022, a review of personnel records identified the following: (a) Testing Person #4 - The Blood Bank initial training had been completed on 12/06/2021. There was no evidence a semiannual evaluation had been performed to date; (b) Testing Person #6 - The Blood Bank initial training had been completed on 12/06/2021. There was no evidence a semiannual evaluation had been performed to date. (2) The records were reviewed with the laboratory manager who stated on 11 /07/2022 at 01:20 pm there were no records to prove the above persons had been evaluated semiannually.