Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472805	05/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cimarron Memorial Hospital	100 South Ellis, Boise City, 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 05/03,04,05/2021. The findings were reviewed with the laboratory director and technical consultant #2 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 technical consultant #2, the laboratory failed to have a written technical consultant competency policy based on the position responsibilities as listed in Subpart M for one of one technical consultant. Findings include: (1) On 05/04/2021, the surveyor reviewed the competency assessment policy. It did not include guidance for assessing the competency of the technical consultant; (2) The surveyor then reviewed personnel records for competency assessments performed during 2019 and 2020. There was no evidence of competencies performed for the technical consultant based on their job responsibilities; (3) The surveyor asked technical consultant #2 if a written policy to evaluate the technical consultant based on job responsibilities was available. Technical consultant #2 stated on 05/04/2021 at 03:10 pm a policy had not been written and the above competencies had not been performed.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of

	the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #2, the laboratory failed to follow the manufacturer's instructions for test timing for a qualitative anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG test for two of three test reports; and failed to follow the manufacturer's instructions for test timing for a blood gas cartridge for one of one test reports. Findings include: HEALGEN COVID-19 IgG/IgM TEST KIT (1) On 05/03/2021 at 10:45 am, technical consultant #2 stated to the surveyor: (a) The laboratory performed anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG testing using the Healgen COVID-19 IgG/IgM test kit. (2) On 05/04/2021, the surveyor reviewed the manufacturer's instructions under the section titled, "Positive Control Testing" which stated: (a) "5. The result should be read in 10 minutes. Do not interpret the result after 15 minutes.". (3) On 05/04/2021, the surveyor reviewed patient testing records from 02/16/2021, 03/04/2021, and 04/20/2021 and identified the following for two of three patient test reports: (a) Patient #041457 - The collection date and time were 02/16/2021 at 11:45 am and approval date and time were 02/16/2021 at 11:45 am; (i) Since the collection date and time were the same as the approval date and time, the surveyor was not able to determine the sample was read within 10 minutes. (b) Patient #042986- The collection date and time were 04/20/2021 at 01:25 pm and approval date and time were 04/20/2021 at 02:21 pm (56 minutes later). (4) The surveyor reviewed the findings with technical consultant #2. Technical consultant #2 stated on 05/04/2021 at 03:13 pm, the laboratory could not prove the specimen was collected, tested, and read within 10 minutes as required by the manufacturer. ARTERIAL BLOOD GAS TESTING (1) On 05/03/2021 at 10:20 am, technical consultant #2 stated the following to the surveyor: (a) The laboratory began performing pH, pCO2, and pO2, testing using the iSTAT1 analyzer (serial number 324888) and CG4+ cartridge on 02/23/2021; (2) On 05/04/2021, the surveyor reviewed the manufacturer's instructions under the section titled, "Mixing and Test Timing (time from collection to cartridge fill) for Chemistry and Blood Gas Cartridge". For test timing, the instructions stated, "Samples for pH, PCO2, PO2, TCO3 and ionized calcium should be tested within 10 minutes."; (3) On 05/04/2021, the surveyor then reviewed a patient testing record on 03/06/2021 and identified the following for one of one patient test report: (a) Patient #043916 - The collection date and time were 03/06/2021 at 07:50 am and the result date and time were 03/09/2021 at 04:51 pm (three days, nine hours and one minute later). (4) The surveyor reviewed the findings with technical consultant #2. Technical consultant #2 stated on 05/04/2021 at 04:26 pm, the laboratory could not prove the specimen was collected and tested within 10 minutes as required by the manufacturer.
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 written policies and procedures, and interview with technical consultant #2, the laboratory failed to have a written procedure for Urine Microscopic testing. Findings include: (1) On 05/03/2021 at 10:35 am, technical consultant #2 stated to the surveyor Urine Microscopic testing was performed in the laboratory; (2) On 05/03/2021, the surveyor reviewed the laboratory policy and procedure manual, and was unable to locate a written procedure for Urine Microscopic testing; (3) The surveyor reviewed the procedure manual with technical consultant #2, who stated on 05/03/2021 at 04:10 pm, the procedure had been written but could not be located.
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 technical consultant #2, the laboratory failed to demonstrate the reportable ranges for two of two new test methods. Findings include: iSTAT 1 ANALYZER AND CG4+ CARTRIDGE (1) On 05/03/2021 at 10:20 am, technical consultant #2 stated the following to the surveyor: (a) The laboratory began performing pCO2, pO2, and Lactate testing using the iSTAT1 analyzer (serial number 324888) and CG4+ cartridge on 02/23/2021; (2) On 05/04/2021, the surveyor reviewed the performance specification records for the new test systems and could not locate documentation to prove the laboratory had demonstrated the reportable ranges; (3) On 05/04/2021, surveyor #2 reviewed the findings with the laboratory manager and the technical consultant. The laboratory manager stated on 10/21/2021 at 02:35 pm, the laboratory did not demonstrate the reportable ranges as indicated above. iSTAT 1 ANALYZER AND CHEM 8+ CARTRIDGE (1) On 05/03/2021 at 10:20 am, technical consultant #2 stated the following to the surveyor: (a) The laboratory began performing Sodium, Potassium, Chloride, Ionized Calcium, Total CO2, Glucose, BUN, Creatinine testing using the iSTAT1 analyzer (serial number 324888) and Chem 8+ cartridge on 06/05/2020; (2) On 05/04/2021, the surveyor reviewed the performance specification records for the new test system and could not locate documentation to prove the laboratory had demonstrated the reportable ranges; (3) On 05/04/2021, surveyor #2 reviewed the findings with the laboratory manager and the technical consultant. The laboratory manager stated on 10/21/2021 at 02:40 pm, the laboratory did not demonstrate the reportable ranges as indicated above.
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 technical consultant #2, the laboratory failed to follow the manufacturer's instructions for performing monthly maintenance procedures for one of three months; and failed to follow the manufacturer's instructions for performing quarterly maintenance for one of one quarter. Findings include: (1) On 05/03/2021 at 10:25 am, technical consultant #2 stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex KX-21N analyzer; (2) On 05/04/20201, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. (a) The requirements for monthly maintenance were as follows: (i) Clean Transducer (ii) Clean Waste Chamber (b) The requirement for quarterly maintenance was as follows: (i) Clean SRV (3) The surveyor then reviewed maintenance records for three months (January 2021 through March 2021) with the following identified: (a) There was no evidence the monthly maintenance had been performed between 02 /12/2021 through 04/04/2021; (b) There was no evidence the first 2021 quarterly maintenance had been performed during the review period. (4) The surveyor reviewed the records with technical consultant #2. Technical consultant #2 stated on 05/04/2021 at 10:15 am, the monthly maintenance and quarterly maintenance had been performed but had not documented as required.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 technical consultant #2, the laboratory failed to perform a negative and positive control material each day of patient testing for one of three days of patient reports. Findings include: (1) On 05/03 /2021 at 10:30 am, technical consultant #2 stated the following to the surveyor: (a) Clostridium difficile testing was performed using the Quik Chek Complete test kit; (b) The laboratory performed negative and positive QC materials each day of patient testing. (2) On 05/04/20201, the surveyor reviewed QC and patient testing records from 02/11/2020 through 09/25/2020. The review showed that negative and positive QC materials had not been performed one of three days of patient testing reviewed. The specific day was on 03/15/2020; (3) The surveyor reviewed the records with technical consultant #2, who stated on 05/04/2021 at 04:10 pm, negative and positive QC materials had not been performed each day of patient testing as indicated above.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to

	the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 written policies and interview with technical consultant #2, the laboratory failed to ensure that written policies provided safety for individuals being transfused for two of six units of packed red blood cells. Findings include: (1) On 05 /03/2021 at 10:55 am, technical consultant #2 stated to the surveyor the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 05/04/2021, the surveyor reviewed the hospital policy regarding transfusion reactions. The policy titled, "BLOOD TRANSFUSION" under the section titled, "PROCEDURE", stated: (a) "8. Obtain from laboratory. Sign out blood on "Blood Bank Issue Log." Hang the blood within 30 minutes of removing from Blood Bank refrigerator.". (b) "Adult: Give 1 unit PRBC over 2-3 hours (DO NOT exceed 4 hours).". (3) The surveyor then reviewed records for two units of PRBCs (Packed Red Blood Cells) that had been transfused between 04/13/2020 through 08/15/2020 for four patients, and identified the following: (a) Hang the blood within 30 minutes (i) Patient #1 - Transfused with one unit of PRBC (unit #W200225128919) on 04/13/2020. The unit was obtained from the laboratory at 06:10 pm and documented the hang time as 07:30 pm (one hour twenty minutes later). (b) Transfusion exceeds four hours (i) Patient #2 - Transfused with one unit of PRBC (unit #W204920465686) on 08/15/2020. The transfusion start time was documented at 01:40 pm and the transfusion end time was documented at 06: 40 (five hours later). (4) On 05/04/2021, the surveyor reviewed the findings with technical consultant #2. Technical consultant #2 stated on 05/04/2021 at 03:45 pm the written policy and procedure for blood administration had not been followed as indicated above.
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 technical consultant #2, the laboratory failed to make appropriate reference ranges available for two of two patient reports. Findings include: (1) On 05/03/2021 at 10:25 am, technical consultant #2 stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex KX-21N analyzer; (2) On 05/03/2021, the surveyor reviewed the written laboratory procedure titled, "Laboratory Assigned Reference Values" which stated (a) 18 years to 999 Female RBC (Red Blood Cells) - 4.20 - 5.40 X 10^6/L (b) 18 years to 999 Males RBC - 4.70 - 6.0 X 10^6/L (2) On 05/03/2021, the surveyor reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 04/30/2021 at 07:32 am; the second report was for an adult male patient with the testing performed on 05/03/2021 at 04:55 pm. Both reports included the same

	reference intervals for the CBC parameter of RBC (Red Blood Cell) which were: (a) RBC - 3.5- 6.0 X 10^6/L (3) The surveyor reviewed the findings with technical consultant #2. The technical consultant #2 stated on 05/03/2021 at 05:00 pm the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC are lower than male reference intervals.
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 technical consultant #2, 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 technical consultant #2, 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 performed. Findings include: (1) On 05/03/2021, the surveyor reviewed records for four persons performing moderate complexity testing in 2019 and 2020. The records showed the evaluation for one of four persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #1 - The 06/23/2020 evaluation had been performed by testing person #3(this person had earned an associates degree in an applied science). (b) Testing Person #2 - The 06/23/2020 evaluation had been performed by testing person #3. (2) The surveyor explained to technical consultant #2 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 masters degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 1 year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). Technical consultant #2 stated to the surveyor on 05/03/2021 at 02: 55 pm, the evaluation had been performed by an individual who did not meet the educational requirements of a technical consultant.