Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472384	08/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Roger Mills Memorial Hospital	501 South L L Males Avenue, Cheyenne, 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 08/22/18 through 08/24/18. The laboratory was found out of compliance with the following CLIA regulations: 493.1409; D6033: Technical Consultant The findings were reviewed with the chief executive officer and laboratory manager/general supervisor during an exit conference performed at the conclusion of the survey.
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 manager/general supervisor, the laboratory failed to review and evaluate proficiency testing results. Findings include: BIASES (1) On the first day of the survey, the surveyor reviewed 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 Chemistry Core Event (i) Chloride - 3 of 5 results exhibited a positive bias (aa) Sample CH-02 - SDI of 2.3 (bb) Sample CH-03 - SDI of 2.2 (cc) Sample CH-05 - SDI of 2.0 (b) Second 2018 Chemistry Core Event (i) Creatinine - 4 of 5 results exhibited a positive bias (aa) Sample CH-06 - SDI of 3.0 (bb) Sample CH-07 - SDI of 2.2 (cc) Sample CH-08 - SDI of 2.0 (dd) Sample CH-10 - 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 manager/general supervisor who stated the biases had not been addressed. FAILURES (1) During the review of proficiency testing records, the surveyor identified the following failures in which there was no evidence of corrective action: (a) First 2017 Chemistry Core Event (i) Sodium - The laboratory failed the result for 1 of 5 samples and attained a score of 80%. The result for sample CH-03 had failed. (b)

	Third 2017 Hematology/Coagulation Event (i) PT (Prothrombin Time) - The laboratory failed the result for 1 of 5 samples and attained a score of 80%. The result for sample HCP-11 had failed. (c) First 2017 Immunohematology Event (i) Antibody Screen - The laboratory failed the result for 1 of 5 samples and attained a score of 80%. The result for sample SER-02 had failed. (d) First 2018 Hematology /Coagulation Event (i) Urine Sediment - The laboratory failed the result for 1 of 5 samples and attained a score of 80%. The result for sample US-01 had failed. (2) The surveyor reviewed the records with the laboratory manager/general supervisor and asked if corrective action had been taken for the above failures. The laboratory manager/general supervisor reviewed the records and stated there was no documentation to prove corrective action had been taken for the failures.
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 a review of records and interview with the laboratory manager/general supervisor, the laboratory failed to provide written instructions to clients collecting and referring hematology and chemistry specimens. Findings include: (1) On the first day of the survey, the laboratory manager/general supervisor stated the following to the surveyor: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex KX-21 N analyzer; (i) Hematology specimens were transported to the laboratory from outside home health agencies. (b) The laboratory performed routine chemistry testing using the Vitros 350 analyzer; (i) Routine chemistry specimens were transported to the laboratory from outside home health agencies. (2) The surveyor asked the laboratory manager/general supervisor if instructions (e.g., client service manual) had been written and provided to the home health agencies which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). The laboratory manager/general supervisor stated specimen handling instructions had not been written and provided to the clients.
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 laboratory manager/general supervisor, the laboratory failed to ensure analyzers were stored as required by the manufacturer. Findings include: (1) On the first day of the

	survey, the laboratory manager/general supervisor stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Sysmex KX-21 N analyzer; (b) Routine Chemistry testing was performed using the Ortho Vitros 350 analyzer; (2) Later on the first day, the surveyor reviewed the manufacturer's environmental requirements for the analyzers. The manufacturer's required the relative humidity be maintained as follows: (a) Sysmex KX-21 N - range of 30-85%; (b) Ortho Vitros 350 - range of 15-75% (3) The surveyor reviewed laboratory records from January 2018 through June 2018. There was no evidence that the humidity of the room, where the analyzers were maintained, had been monitored at an acceptable range of 30-75% to accomodate both analyzers; (4) The surveyor asked the laboratory manager/general supervisor if the humidity of the room, where the hematology and chemistry analyzers were maintained, was being monitored. The laboratory manager/general supervisor stated it was not monitored.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's package insert, observation, and interview with the laboratory manager/general supervisor, the laboratory failed to document the open date on quality control vials. Findings include: (1) On the first day of the survey, the laboratory manager/general supervisor stated the following to the surveyor: (a) The laboratory performed CBC (Complete Blood Count) testing on the Sysmex KX-21N analyzer; (b) Three levels of EightCheck-3WP X-Tra control materials were analyzed each day of patient testing performed on the analyzer. (2) On the second day of the survey, the surveyor observed the current quality control materials in use: 1 vial of low control lot #81430710, 1 vial of normal control lot #81430711, and 1 vial of high control lot #81430712. The vials had not been dated with the open date; (3) The surveyor reviewed the manufacturer's package insert for the control materials. The insert stated, "Unused product is stable for 14 days when promptly refrigerated after each use."; (4) The surveyor reviewed the instructions with laboratory manager /general supervisor. The laboratory manager/general supervisor stated vials should have been dated when put 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 laboratory manager/general 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/general supervisor stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Sysmex KS-21N 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 and monthly maintenance were as follows: (a) Weekly (i) Clean SRV Tray (b) Monthly (i) Clean Waster Chamber (Rinse Sequence) (ii) Clean Transducer (Rinse Sequence) (3) The surveyor then reviewed maintenance records for 12 months (January 2017 through June 2017 and January 2018 through June 2018) and identified the following: (a) Weekly maintenance had not been documented as performed between: (i) 01/01/17 and 01/12 /17 (ii) 01/12/17 and 01/26/17 (iii) 02/06/17 and 02/15/17 (iv) 03/02/17 and 03/13/17 (v) 05/02/17 and 05/13/17 (vi) 05/13/17 and 06/02/17 (vii) 02/07/18 and 03/02/18 (viii) 05/02/18 and 05/14/18 (ix) 05/14/18 and 06/13/18 (b) Monthly maintenance had not been documented as performed between: (i) 04/10/17 and 06/20/17 (ii) 01/09/18 and 03/07/18 (iii) 03/07/18 and 05/14/18 (4) The surveyor reviewed the records with the laboratory manager/general supervisor, who stated the weekly and monthly maintenance had not been performed 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 the laboratory manager/general supervisor, the laboratory failed to perform control procedures each day of blood bank testing; and failed to perform a negative and positive control each day of CKMB and Troponin I testing. Findings include: BLOOD BANK TESTING (1) On the first day of the survey, the laboratory manager/general supervisor stated to the surveyor that the laboratory performed the following blood bank testing: (a) Type and Screen Testing - consisted of ABO/Rh and Antibody Screen; (b) Crossmatch Testing - consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)); (2) On the second day of the survey, the surveyor reviewed records for blood bank testing performed from March 2018 through July 2018. Quality control testing had not been performed for 1 of 8 days when patient Type and Screen or Crossmatch testing had been performed as follows: (a) A Type and Screen was performed on 04/25/18. A positive ABO control, positive and negative Rh controls, positive and negative AHG (Anti-human globulin) controls, and positive Antibody Screen control had not been documented as performed; (3) The surveyor reviewed the records with the laboratory manager /general supervisor, who stated there was no evidence quality control testing had been performed as indicated above. CKMB and TROPONIN I TESTING (1) On the first day of the survey, the laboratory manager/general supervisor stated to the surveyor CKMB and Troponin I testing were performed using the CKMB cartridge and cTnI cartridge with the Abbott iSTAT analyzer. (2) The surveyor asked the laboratory manager/general supervisor if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory manager/general supervisor stated an IQCP had not been developed. Therefore, the surveyor determined negative and

	positive QC (quality control) materials must be performed each day of patient testing; (3) The surveyor reviewed QC and patient testing records for January 2018. The review indicated negative and positive QC materials had not been performed 3 of 8 days of patient testing. The specific days were as follows: (a) CKMB (i) patient testing on 01/14/18 (b) Troponin I (i) patient testing on 01/14/18 (ii) patient testing on 01/26/18 (4) The surveyor reviewed the records with the laboratory manager/general supervisor who stated negative and positive QC materials had not been performed each day of patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 laboratory manager/general supervisor, the laboratory failed to establish statistical parameters for unassayed Protime control materials. Findings include: (1) On the first day of the survey, the laboratory manager/general supervisor stated the following: (a) The Hemochron Jr. Signature + analyzer was used to perform testing for the analyte Protime (PT) using the Citrate PT cuvettes; (b) Normal and Abnormal controls were tested each 30 days and with new lot numbers of cuvettes. (2) On the second day of the survey, the surveyor reviewed the manufacturer's quality control package inserts. The inserts did not contain statistical parameters (i.e., means, standard deviations, etc.) for evaluating PT control results, verifying the controls were unassayed; (3) The surveyor then reviewed quality control records from January 2017 through the July 2018. For 19 of 19 months of quality control testing, there was no evidence that control results had been evaluated for acceptability using established statistical parameters; (4) The findings were discussed with the laboratory manager/general supervisor who stated that statistical parameters had not been established for PT controls. NOTE: This deficiency was cited on the previous recertification survey performed 01/04/17 and 01/05/17.
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 laboratory manager/general supervisor, the laboratory failed to follow the manufacturer's specifications for establishing quality control ranges. Findings include: (1) On the first day of the survey, the laboratory manager/general supervisor stated the following: (a) The Hemochron Jr. Signature + analyzer was used to perform testing for the analyte INR (International Normalized Ratio) and PT (Prothrombine Time) using the Citrate PT cuvettes; (b) Normal and abnormal controls were tested each 8 hours of patient testing. (2) On the second day of the survey, the surveyor reviewed the manufacturer's instructions (package inserts) for the control materials which stated, "ITC recommends that each institution establish its own expected range of response based on the mean +/- 2 standard deviations of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range"; (3) The surveyor then reviewed quality control records from March 2018 through July 2018. For 2 of 2 lot numbers of quality control materials, the laboratory failed to follow the manufacturer's instructions of at least 20 repeated test results. The following was identified: (a) Citrate PT/INR (i) Normal Control lot# F7DNC010 - put into use 04/16/18 (aa) The laboratory established control ranges using 18 repeated test results (d) Citrate PT/INR (i) Abnormal Control lot# H7DAC008 - put into use 04/16/18 (aa) The laboratory established control ranges using 18 repeated test results (4) The findings were reviewed with the laboratory manager/general supervisor who stated the laboratory had not followed the manufacturer's instructions for establishing quality control ranges. NOTE: This deficiency was cited on the previous recertification survey performed 01/04/17 and 01 /05/17.
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 laboratory manager/general supervisor 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. Findings include: (1) On the first day of the survey, the laboratory manager/general supervisor stated to the surveyor Arterial Blood Gas testing (pH, PCO2, PO2) was performed using the G3+ cartridge with the Abbott iSTAT analyzer. (2) The surveyor asked the laboratory manager/general supervisor if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory manager/general supervisor stated an IQCP had not been developed. Therefore, the surveyor determined one sample of QC (quality control) materials must be performed each 8 hours of patient testing; (3) The surveyor reviewed QC and patient testing records for January 2018. The review indicated QC materials had not been performed each 8 hours of patient testing for 1 of 3 days, the specific day was 01/16/18; (4) The surveyor reviewed the records with the laboratory manager/general supervisor who stated QC materials had not been performed each 8 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, and interview with the laboratory manager/general supervisor, the laboratory failed to ensure units of blood were stored under appropriate conditions that included an adequate temperature alarm system that is regularly inspected. Findings include: (1) On the second day of the survey, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (2) The surveyor reviewed 35 refrigerator charts dated from December 2017 through July 2018. The review indicated that 3 of 35 charts had not been changed by the 7th day of usage. The findings include: (a) Chart #1 - The chart was put into use on 12/07/17 and removed on 12/19/17 (12 days); (b) Chart #5 - The chart was put into use on 01/02/18 and removed 01/11/18 (9 days); (c) Chart #16 - The chart was put into use on 03/09 /18 and removed 03/19/18 (10 days); (3) The surveyor reviewed the charts with the laboratory manager/general supervisor, who stated the charts had not been changed by the 7th day of usage as indicated above. NOTE: This deficiency was cited on the previous recertification survey performed 01/04/17 and 01/05/17.
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 manager/general 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. NOTE: This deficiency was cited on the previous recertification survey performed 01/04/17 and 01/05/17.
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 manager/general supervisor, the technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: (1) One the first day of the survey, the surveyor reviewed records for 3 persons performing moderate complexity testing in 2017 and 2018. The records verified the evaluations for 2 of 3 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 06/15/17 annual evaluation had been performed by testing person #1 (this person had earned an associate degree); (ii) The 04/25/18 annual evaluation had been performed by testing person #1. (b) Testing Person #3 (i) The 06 /15/17 annual evaluation had been performed by testing person #1; (ii) The 04/25/18 annual evaluation had been performed by testing person #1. (2) The surveyor explained to the laboratory manager/general 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).
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's

	procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the laboratory manager/general supervisor, testing personnel failed to follow the laboratory's policy for performing patient testing. Findings include: (1) On the first day of the survey, the laboratory manager/general supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex KX-21N analyzer; (2) On the second day of the survey, the surveyor reviewed the policy titled, "Roger Mills Memorial Hospital Laboratory Hematology": (a) Under the heading "Manual Differential: (i) "Manual differentials shall be performed using the following criteria: WBC > 14" (3) The surveyor randomly reviewed 14 patient CBC reports for testing performed between March 2017 and April 2018 and identified testing personnel had not followed the above policy for 2 patients: (a) The patient specimen had been tested on 03/09/17 and met the laboratory criteria (WBC result: 15.5 X 10^ 3) for performing a manual differential. (b) The patient specimen had been tested on 04/14/18 and met the laboratory criteria (WBC: 15.6 X 10^3) for performing a manual differential. (4) The surveyor reviewed the reports with the laboratory manager/general supervisor. The laboratory manager/general supervisor stated testing personnel did not follow the laboratory policy for the two patients.