Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0050504	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mary Mahoney Memorial Health Center	12716 Ne 36th Street, Spencer, 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 06/04/19. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory director/technical consultant 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 supervisor, the laboratory failed to maintain a copy of all records, and the laboratory director and/or testing person failed to sign proficiency testing attestation statements. Findings include: (1) During the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following for 5 of 11 events: (a) First 2018 Chemistry Miscellaneous Event - The attestation statement had not been signed by the laboratory director; (b) Second 2018 Chemistry Miscellaneous Event - The attestation statement had not been signed by the laboratory director and testing person(s); (c) Second 2018 Chemistry Core Event - The attestation statement and copy of the

	submitted results had not been maintained; (d) Second 2018 Hematology Event - The attestation statement had not been signed by the laboratory director; (e) First 2019 Chemistry Core Event - The attestation statement had not been signed by the laboratory director. (2) The surveyor reviewed the findings with the laboratory supervisor who stated the attestations had not been signed and the records had not been maintained as indicated above.
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 and interview with the laboratory supervisor, the laboratory failed to have a written clinical consultant and technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) During the survey, the surveyor reviewed personnel records for competency assessments performed during 2017, 2018, and to date in 2019. There was no evidence competencies had been performed for the clinical consultant and technical consultant, based on their job responsibilities; (2) The surveyor asked the laboratory manager if a written policy to evaluate the clinical consultant and technical consultant based on job responsibilities was available and if competencies had been performed during the review period. The laboratory supervisor stated a policy to evaluate the clinical consultant and technical consultant based on job responsibilities had not been written; and competencies 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) During the survey, the surveyor reviewed 2018 and 2019 Hematology proficiency testing records. The following failure was identified, for which corrective action documentation could not be located: (a) Second 2018 Event (i) WBC (White Blood Cell) - The laboratory failed the result for 1 of 5 samples (XE-06), and attained a score of 80%. (2) The surveyor asked the laboratory supervisor if corrective action had been taken for the failure. After reviewing the records, the laboratory manager stated corrective action had not been taken for the failure.
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 the policy and procedure manual and interview with the laboratory supervisor, the laboratory failed to have written procedures that explained the current practices and procedures being performed in the laboratory. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor microscopic urine sediment examinations were performed in the laboratory by placing a drop of the sediment on a microscope slide and using a coverslip; (2) The surveyor reviewed written policies and procedures. The procedure titled, "Microscopic Urinalysis Procedure" did not explain the current procedure for performing microscopic urine sediment examinations. The procedure described using the "Quick-Prep Urinalysis Kit" which includes the following materials: (a) Quick-Prep collection tubes (b) Quick-Prep transfer pipets (c) Quick-Read Precision Cell slide (a plastic slide containing 10 wells to dispense urine sediment) (3) The surveyor reviewed the findings with the laboratory supervisor who stated the laboratory did not use the Quick-Prep Urinalysis kit and the procedure in the manual did not reflect the laboratory's current method of performing microscopic urine sediment examinations.
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) At the beginning of the survey, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) Later during the survey, the surveyor reviewed the manufacturer's weekly maintenance requirements as stated on the manufacturer's maintenance logs: (a) Power Down IPU (3) The surveyor then reviewed maintenance records from June 2018 through the day of the survey. There was no evidence the weekly maintenance had been performed: (a) Between 06/15/18 and 07/01/18 (b) Between 08/23/18 and 09/10/18 (c) Between 09/28/18 and 01/10/19 (d) Between 01/26/19 and 02/08/19 (e) Between 02/22/19 and 03/08/19 (f) After 03/29 /19 (4) The surveyor reviewed the records with the laboratory supervisor, who stated the weekly maintenance had not been documented as performed as indicated 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 laboratory supervisor, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor Urine Microalbumin and Creatinine testing were performed on the Siemens DCA Vantage analyzer; (2) The surveyor reviewed 2017, 2018, and 2019 records for the analyzer (since calibration procedures were not routinely performed, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months); (3) The surveyor could not locate records to verify calibration verification procedures had been performed since 11/12/18 (due in May 2019); (4) The surveyor reviewed the findings with the laboratory supervisor and asked if calibration verification procedures had been performed since 11/12/18. The laboratory supervisor stated that calibration verification procedures had not been performed since 11/12/18.
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 and interview with the laboratory supervisor, the laboratory failed to verify the stated value of control materials before they were put into use. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated the following to the surveyor: (a) The laboratory performed Urine Microalbumin and Creatinine testing using the Siemens DCA Vantage analyzer; (b) Two levels of manufacturer control materials were analyzed each day of patient

	testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) Later during the survey, the surveyor reviewed records for 2 control lot numbers. There was no evidence the provided ranges were verified before the lot numbers were put into use for 2 of 2 lot numbers as follows: (a) Low control lot #0053L and high control lot #0053H - Put into use on 05/03/18 and were currently in use during the survey. (3) The findings were reviewed with the laboratory supervisor who stated the manufacturer's ranges had not been verified before the above lot numbers had been put into use.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. 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 ensure corrective action taken for unacceptable humidity readings were complete. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000I analyzer; (2) The surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) The surveyor reviewed laboratory humidity records from July 2018 through May 2019 and identified days the humidity readings were less than 30% for 3 of 11 months, with corrective action documented as follows: (a) February 2019 - 12 of 25 humidity readings were documented as less than 30% (days 09,13,15,16,17,18,19,21,22,23,27,28). The corrective action documented for each unacceptable humidity reading stated, "Ran Humidifier"; (b) March 2019 - 6 of 21 humidity readings were documented as less than 30% (days 01,04,05,07,11,18). The corrective action documented for each unacceptable humidity reading stated, "Ran Humidifier"; (c) April 2019 - 3 of 22 humidity readings were documented as less than 30% (days 01,02,12). The corrective action documented for each unacceptable humidity reading stated, "Ran Humidifier". (4) The surveyor reviewed the records with the laboratory supervisor and asked if the humidity had been taken after running the humidifier to ensure the corrective action was effective and resolved the problem. The laboratory supervisor stated the humidity had not been checked and documented after running the humidifier; (5) The surveyor determined the corrective action was not complete since there was no documentation to support that running the humidifier resulted in an acceptable humidity reading.
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 make appropriate reference ranges available. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer; (2) Later during the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult female with the testing performed on 05/31/19; the second report was for an adult male with the testing performed on 06/04/19. Both reports included the same reference intervals for the CBC parameters of Hematocrit and RBC (Red Blood Cell) which were: (a) Hematocrit - 37-51% (b) RBC - 4.40-6.30 (x 10-6 /uL) (3) The surveyor reviewed the findings with the laboratory supervisor, who stated the patient reports did not include gender specific reference ranges for Hematocrit and RBC. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit 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 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) During the survey, the surveyor reviewed records for 3 persons performing moderate complexity testing in 2017, 2018, and to date in 2019. The records indicated 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 - The 01/18/17 and 09/27/18 evaluations had been performed by the laboratory supervisor (this person had earned an associate degree in science); (b) Testing Person #3 - The 05/24/19 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).