Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0050504	07/01/2021
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 07/01/2021. The findings were reviewed with the laboratory director and laboratory supervisor 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 and interview with the laboratory supervisor, the laboratory failed to have a written clinical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) The surveyor reviewed personnel records for competency assessments performed during 2019, 2020, and to date in 2021. There was no evidence competencies had been performed for clinical consultant based on job responsibilities; (2) The surveyor asked the laboratory supervisor if a written policy to evaluate the clinical consultant, based on job responsibilities, was available and if competencies had been performed during the review period. The laboratory supervisor stated to the surveyor on 07/01/2021 at 03: 38 pm, a policy to evaluate the clinical consultant based on job responsibilities had not been written; and competencies had not been performed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I 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 verify the accuracy of Wet Prep analysis at least twice annually. Findings include: (1) On 07/01/2021 at 09:40 am, the laboratory supervisor stated to the surveyor the laboratory performed Wet Prep analysis; (2) The surveyor reviewed 2019 and 2020 records, which showed the testing had not been verified for accuracy twice in 2019 and 2020. Wet Prep analysis had not been verified for accuracy prior to 05/19/2020; (3) The surveyor reviewed the records with the laboratory supervisor who stated on 07/01/2021 at 03:48 pm, Wet Prep analysis had not been verified for accuracy at least twice annually in 2019 and 2020.
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 follow written procedures for CBC (Complete Blood Test) testing performed for 6 of 9 quality control lot numbers. Findings include: (1) On 07/01/2021 at 09:35 am, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) The surveyor reviewed written laboratory procedure titled, "Lab Policies Volume:2" under the section titled, "V. QUALITY CONTROL" stated, (a) "F. Auto-Set Targets" (i) "Parallel test new controls by analyzing each level of control a minimum of twice a day for 5 days prior to expiration of the previous lot. After a minimum of 10 data points are accumulated, auto-set the targets," (3) The surveyor reviewed 9 QC (quality control) lot numbers. For 6 of 9 lot numbers there was no indication the laboratory staff followed their written procedure as follows: (a) Lot# 03500804 ran 1 time before put into use on 01/10/2021; (b) Lot# 03500805 ran 1 time before put into use on 01/10/2021; (c) Lot# 03500806 ran 1 time before put into use on 01/10/2021; (d) Lot# 10860804 ran 1 time before put into use on 04/19/2021; (e) Lot# 10860805 ran 1 time before put into use on 04/19/2021; (f) Lot# 10860806 ran 1 time before put into use on 04/19/2021. (4) The surveyor reviewed the findings with the laboratory supervisor. The laboratory supervisor stated on 07/01/2021 at 04:20 pm that the procedure had not been followed as indicated above.
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 the procedure manual and interview with the laboratory supervisor, the laboratory failed to ensure written policies and procedures had been

	approved, signed, and dated by the laboratory director. Findings include: (1) On 07/01 /2021 at 09:35 am, the laboratory supervisor stated to the surveyor the laboratory performed the following moderately complex testing: (a) Routine CBC(Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer; (b) Microalbumin testing was performed using the Siemens DCA Vantage analyzer; (c) Urine Sediment examinations; (d) Wet Prep examinations. (2) The surveyor reviewed the following laboratory manuals titled,"Lab Policies Volume:1" and "Lab Policies Volume:2", which contained written policies and procedures. There was no indication the manual had been approved, signed, and dated by the laboratory director; (3) The surveyor showed the manual to the laboratory supervisor. The laboratory supervisor stated on 07/01/2021 at 04:10 pm, the documentation to prove the contained policies and procedures had been signed and dated by the laboratory director could not be located.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. 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 verifying morphology flags for 3 of 6 patient reports. Findings include: (1) On 07 /01/2021 at 09:35 am, the laboratory supervisor stated that CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) The surveyor reviewed the manufacturer's instructions for verifying morphology flags obtained on the analyzer. The following were examples of flags, with the corresponding instructions: (a) Anemia - "Verify RBC morphology on slide" (b) Dimorphic Population - "Verify RBC morphology on slide" (c) HGB Defect - "Verify RBC morphology on slide" (d) Lymphocytosis - "Review manual smear" (e) Microcytosis - "Verify RBC morphology on slide" (f) Monocytosis - "Review manual smear" (g) Neutrophilia - "Review manual smear" (h) PLT Abn Distribution - "Verify presence on slide" (i) PLT Clump(s) - "Verify on slide" (j) RBC Abn Distribution - "Verify presence on slide" (3) The surveyor randomly reviewed 6 patient records which contained morphology flags from CBC testing performed on 09/01/2020, 09/04/2020, 09/21/2020, 09/22/2020, and 01/08/2021. For 3 of the records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags. The findings for the 3 records were: (a) Testing was performed on 09/01/2020 at 02:12 pm, with RBC Abn Distribution, Dimorphic Population, and Anemia flags obtained; (b) Testing was performed on 09/01/2020 at 11:18 am, with a Microcytosis flag obtained; (c) Testing was performed on 09/22/2020 at 02:07 pm, with an Monocytosis flag obtained. (4) The surveyor reviewed the records with the laboratory supervisor, who stated on 07/01/2020 at 04:41 pm that the flags obtained for the above 3 patients had not been verified
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions and interview with the laboratory supervisor, the laboratory failed ensure quality control materials were not used beyond open vial stability for 1 of 1 lot numbers. Findings include: (1) On 07/01/2020 at 09: 45 am, the laboratory supervisor stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer; (2) The surveyor observed at 10:00 am the following control material stored in the laboratory refrigerator:: (a) Sysmex e-CHECK Tri-Level control materials: (i) 1 bottle of low control lot# 11520804 (ii) 1 bottle of normal control lot# 1152805 (iii) 1 bottle of high control lot# 11520806 (3) The surveyor asked the laboratory supervisor to explain what the controls were used for. The laboratory supervisor explained the following: (a) Sysmex e-CHECK Tri-Level controls were used to perform quality control procedures for CBC testing performed on the Sysmex XS-1000i analyzer. (4) The surveyor reviewed the manufacturer's open date stability instructions, which stated the following: (a) "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8C."; (b) The quality control materials had been dated as opened on 06/14/2021 and were available for use on the day of the survey (17 days). (5) The surveyor reviewed the instructions and the open dates on the control bottles with the laboratory supervisor, who stated on 07/01/2021 at 10:00 am the controls were available for use beyond the manufacturer's open vial expiration date.
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 perform maintenance procedures as required by the manufacturer for 1 of 11 months. Findings include: SYSMEX XS-1000i ANALYZER (1) On 07/01/2021 at 09:50 am, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) The surveyor reviewed the manufacturer's weekly maintenance requirement for the analyzer, as stated on the manufacturer's maintenance log titled "XS-1000i MAINTENANCE LOG", which was: (a) "Power Down IPU" (3) Maintenance records were reviewed by the surveyor for 11 months (January 2020 through November 2020). The weekly maintenance had not been documented as performed between: (a) 04/24/2020 and 06/05/2020 (4) The surveyor reviewed the records with the laboratory supervisor. The laboratory supervisor stated on 07/01/2020 at 04:00 pm, there was no evidence the above maintenance had been performed as required. SIEMENS DCA VANTAGE ANALYZER (1) On 07/01/2021 at 09:55 am, the laboratory supervisor stated to the surveyor Microalbumin testing was performed on the Siemens DCA Vantage analyzer; (2) The surveyor reviewed the manufacturer's weekly maintenance requirement for the analyzer, as stated on the manufacturer's maintenance log which was: (a) "CLEAN EXTERIOR"; (b) "CLEAN

	BAR CODE WINDOW" (3) Maintenance records were reviewed by the surveyor for 11 months (January 2020 through November 2020). The weekly maintenance had not been documented as performed between: (a) 04/27/2020 and 06/01/2020 (4) The surveyor reviewed the records with the laboratory supervisor. The laboratory supervisor stated on 07/01/2020 at 04:04 pm, there was no evidence the above maintenance had been performed as required.
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 manager, the laboratory failed to follow the function check protocol to ensure the urine centrifuge was functioning properly for 2 of 2 function checks performed. Findings include: (1) On 07/01/20201 at 09:35 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed microscopic urine sediment examinations; (b) The laboratory used the Unico centrifuge to process urine at a speed between 1500 - 2000 rpm (revolutions per minute) for 5 minutes; (2) The surveyor reviewed the function check policy titled, "Centrifuge Calibration" which stated, "Centrifuges will be calibrated annually for the RPM's and Timer to ensure the speed and times are within acceptable limit and to ensure the quality of testing is not compromised." (a) "Acceptable RPM's will be between 1500 - 2000 RPM's for Urinalysis." (b) "Acceptable time limit will be 4.9 - 5.0 minutes for Urinalysis." (3) The surveyor reviewed the centrifuge maintenance records for 2019 and 2020. The following was identified for 2 of 2 checks performed: (a) 10/20/2019 - The speed had been checked at 2420 rpm an the timer had been checked at 10 minutes, which were not the speed and time settings that urine specimens were processed; (b) 10/21/2020 - The speed had been checked at 3348 rpm an the timer had been checked at 10 minutes, which were not the speed and time settings that urine specimens were processed. (4) The surveyor reviewed the findings with the laboratory manager who stated on 07/01/2021 at 01:15 pm, the laboratory did not ensure the urine centrifuge was functioning properly as indicated above.
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 failed to have control procedures that monitored the accuracy and precision of the testing process for 3 of 3 quality control lot numbers. Findings include: (1) On 07/01/2021 at 09:35 am, the laboratory supervisor stated the following: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer; (b) Three levels (low, normal, and high) of Sysmex e-check XS quality control materials were tested each day that patient testing was performed. (2) The surveyor reviewed quality control records. The records indicated that low control (lot #10400804), normal control (lot #10400805), and high control (lot #10400806) had been put into use on 03/05/2021 and used through 04/19/2021; (3) The surveyor requested QC (quality control) records (i.e., Levey-Jennings data) for the above testing performed from 03/05/2021 through 04/19/2021 to ensure QC had been monitored for variances (i.e. shifts, trends, biases). The lead tech stated on 07/01/2021 at 04:35 pm, there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances during the review period because data had not been printed and maintained. The surveyor was able to verify that QC had been performed each day of patient testing, however, there was no documentation the data had been reviewed for variances by the laboratory.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. 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 patient test reports included the address of the laboratory location where the testing was performed. Findings include: (1) On 07/01/2021 at 09: 45 am, the laboratory supervisor stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer. (2) The surveyor reviewed a patient CBC report (CBC testing performed on 07/01 /2021). The report did not include the address of the laboratory location; (3) The surveyor reviewed the report with the laboratory supervisor. The laboratory supervisor stated on 07/01/2021 at 03:45 pm, the reports did not include the address of the laboratory location.
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 for 1 of 4 competency evaluations. Findings include: (1) On 07/01/20201, the surveyor

	reviewed records for 4 persons performing moderate complexity testing in 2019, 2020, and 2021. The records showed the evaluations for 1 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- The 04/29/2019 and 08/04/2020 evaluations had been performed by the laboratory supervisor (this person had earned an associate degree in an applied science). (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). The laboratory supervisor stated to the surveyor on 07 /01/2021 at 12:15 pm, the evaluations had been performed by an individual who did not meet the years of experience of a technical consultant.