Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0965880	07/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Muskogee Pediatrics & Family Health Solutions	3505 W Broadway, Muskogee, 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 07/11/2024. The laboratory was found out of compliance with the following CLIA Conditions: 493.1215; D5024: Hematology 493.1405; D6000: Laboratory Director The findings were reviewed with owner #1, owner #2, and testing person #2 at the conclusion of the survey.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of records, observation of the laboratory, and interview with testing person #2, the laboratory failed to follow the manufacturer's instructions for expiration dates of waived testing materials. Findings include: (1) On 07/11/2024 at 11:52 am, observation of the laboratory identified the following expired materials which appeared to be available for use: (a) One box of Beckman Coulter Hemoccult slides, lot 1751, manufacturer's expiration date 08/2018; (b) One vial of Beckman Coulter Developer/15mL, lot 61777, manufacturer's expiration date 06/2019; (c) One box of Sekisui Diagnostic - Osom Mono test kit, lot B221405, manufacturer's expiration date 09/2023. (2) The findings were reviewed with testing person #2, who stated on 07/11/2024 at 11:57 am the test materials had expired and were available for use.
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 testing person #2, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee and the analyst(s) for five of five hematology events reviewed in 2023 and 2024. Findings include: (1) A review of the first, second, third of 2023; and first and second of 2024 Hematology proficiency testing records identified the attestation statements had not been signed by the laboratory director or designee and the analyst(s); (2) The findings were reviewed with testing person #2 who stated on 07/11/2024 at 12:35 pm, the attestation statements had not been signed as stated above.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #2, office manager, and owner #1, the laboratory failed to participate in one of five proficiency testing (PT) events reviewed in 2023 and 2024. Findings include: (1) On 07/11/2024, a review of PT records for 2023 through 2024 identified the laboratory attained a 0% score for the analytes White Blood Cell Count, Red Blood Cell Count, Hemoglobin, Hematocrit, MCV (Mean Corpuscular Volume), Platelet Count, and White Blood Cell Differential, for the first 2024 Hematology event, due to a failure to participate; (2) A review of records with the office manager and testing person #2 identified the following: (a) No documentation to prove the samples had been tested in the laboratory (i.e., instrument printouts); (b) A WSLH Proficiency Testing Data Submission Report dated 03/11/2024 at 09:16 am, with dashes in the specimen results column instead of quantitative results; (c) No documentation to explain what occurred to cause the laboratory to not participate in the event. (3) Testing person #2 and owner #1 stated on 07/11/2024 at 03:00 pm the laboratory participated in the PT event, had submitted the results electronically on 03/11/2024 at 09:16 am, but the complete documentation could not be located during the survey; (4) Examples of patient Complete Blood Count testing performed during the time the laboratory did not

	participate in proficiency testing are as follows: (a) Patient # 48 test performed on 03 /15/2024 (b) Patient # 49 test performed on 03/19/2024 (c) Patient # 50 test performed on 04/08/2024 (d) Patient # 51 test performed on 04/17/2024 (e) Patient # 52 test performed on 04/26/2024 (f) Patient # 53 test performed on 06/18/2024 (g) Patient # 54 test performed on 06/18/2024
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records and interview with owner #1 and testing person #2, the laboratory failed to ensure the requirements were met for the specialty of Hematology for CBC testing during the review period of January 2023 through June 2024. Findings include: (1) The laboratory failed to ensure quality control (QC) materials were not used beyond the expiration date. Refer to D5417; (2) The laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429; (3) The laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process. Refer to D5441; (4) The laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed. Refer to D5791; (5) The laboratory failed to ensure patient test reports included the name, as stated on the CLIA certificate, address of the laboratory location where the testing was performed, unique patient identifier, and normal patient reference ranges. Refer to D5805.
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 records and interview with testing person #2, the laboratory failed to ensure quality control (QC) materials were not used beyond the expiration date for three of 15 lot numbers reviewed. Findings include: (1) On 07/11/2024 at 12: 45 pm, testing person #2 stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Medonic M-Series analyzer; (b) Three levels of Boule Conn-Diff Tri-Level QC (Quality Control) materials were tested each day of patient testing. (2) A review of records for 15 lot numbers of QC materials used from 03/29/2023 through 12/29/2023 identified controls had been used beyond the manufacturer's expiration date for three of 15 lot numbers reviewed as follows: (a) Low control lot #22308-01 ran on 12/27/2023, 12/28/2023, and 12/29/2023. The manufacturer's expiration date was 12/22/2023; (b) Normal control lot #22308-02 ran on 12/27/2023, 12/28/2023, and 12/29/2023. The manufacturer's expiration date was 12/25/2023; (c) High control lot #22308-03 12 ran on 12/27/2023, 12/28/2023, and 12 /29/2023. The manufacturer's expiration date was 12/26/2023. (3) A review of patient

	records confirmed patient CBC results had been reported on the following dates when the laboratory had used expired QC materials to assess the acceptable performance of the analyzer: (a) Patient # 24 testing performed on 12/28/2023, and 12/29/2023 (b) Patient # 30 testing performed on 12/27/2023 (c) Patient # 31 testing performed on 12 /27/2023 (d) Patient # 32 testing performed on 12/27/2023 (e) Patient # 33 testing performed on 12/28/2023 (f) Patient # 34 testing performed on 12/29/2023 (g) Patient # 35 testing performed on 12/29/2023 (4) Findings were reviewed with owner #1 and testing person #2 who stated on 07/11/2024 at 03:00 pm, the controls had been used beyond the expiration dates.
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 and interview with testing person #2, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Medonic M-Series analyzer during the review period of January 2023 through June 2024. Findings include: (1) On 07/11/2024 at 12:45 pm, testing person #2 stated CBC (Complete Blood Count) testing was performed using the Medonic M-Series analyzer; (2) A review of the manufacturer's instruction manual titled, "Medonic M-series User's Manual", Section 8, required the following maintenance procedures: (a) Monthly: (i) Clean using hypochlorite solution and perform clot prevention using enzymatic solution (b) Six Months: (ii) Clean using hypochlorite solution, enzymatic solution, and detergent cleaner (3) A review of maintenance logs from January 2023 through June 2024 identified maintenance had not been documented as performed for the following: (a) Monthly: (i) Between 02/01 /2023 and 04/01/2023 (ii) Between 04/01/2023 and 06/01/2023 (iii) Between 07/10 /2023 and 09/01/2023 (b) Six Months: (i) Between 01/01/2023 and 11/01/2023 (ii) Between 11/01/2023 and 06/30/2024 (4) The records were reviewed with owner #1 and testing person #2 who stated on 07/11/2024 at 04:45 pm, maintenance procedures had not been documented as performed as stated above; (5) Refer to D5441 for examples of patient testing performed when maintenance had not been documented as performed.
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 owner #1 and testing person #2 the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for 17 of 17 months reviewed for the testing performed using the Medonic M-Series analyzer. Findings include: (1) On 07/11/2024 at 12:45 pm, testing person #2 stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Medonic M-Series analyzer; (b) Three levels of Boule Conn-Diff Tri-Level QC (Quality Control) materials were tested each day of patient testing. (2) A review of records from February 2023 through June 2024 identified no evidence, such as Levey-Jennings graphs and cumulative statistical data, to prove that QC results had been monitored for variances (i.e., biases, shifts, or trends); (3) Interview with owner #1 and testing person #2 on 07/11/2024 at 3:51 pm confirmed that QC data to include Levey-Jennings graphs and cumulative statistical data had not been printed and reviewed for the period stated above; (4) The following were examples of patient CBC testing performed during this timeframe: (a) Patient # 1 testing performed on 02/03/2023 (b) Patient # 2 testing performed on 02/15/2023 (c) Patient # 3 testing performed on 02/28/2023 (d) Patient # 4 testing performed on 03/01 /2023 (e) Patient # 5 testing performed on 03/13/2023 (f) Patient # 6 testing performed on 03/30/2023 (g) Patient # 7 testing performed on 05/05/2023 (h) Patient # 8 testing performed on 05/18/2023 (i) Patient # 9 testing performed on 05/26/2023 (j) Patient # 10 testing performed on 07/18/2023 (l) Patient # 11 testing performed on 07/21/2023 (m) Patient # 12 testing performed on 08/10/2023 (n) Patient # 13 testing performed on 08/23/2023 (o) Patient # 14 testing performed on 08/28/2023 (p) Patient # 15 testing performed on 09/05/2023 (q) Patient # 16 testing performed on 09/07/2023 (r) Patient # 17 testing performed on 09/12/2023 (s) Patient # 18 testing performed on 09 /19/2023 (t) Patient # 19 testing performed on 09/25/2023 (u) Patient # 20 testing performed on 10/12/2023 (v) Patient # 21 testing performed on 10/16/2023 (w) Patient # 22 testing performed on 10/19/2023 (x) Patient # 23 testing performed on 10 /30/2023 (y) Patient # 24 testing performed on 11/06/2023, 12/28/2023, and 12/29 /2023 (z) Patient # 25 testing performed on 11/15/2023 (aa) Patient # 26 testing performed on 11/28/2023 (bb) Patient # 27 testing performed on 12/11/2023 (cc) Patient # 28 testing performed on 12/13/2023 (dd) Patient # 29 testing performed on 12/21/2023 (ee) Patient # 30 testing performed on 12/27/2023 (ff) Patient # 31 testing performed on 12/27/2023 (gg) Patient # 32 testing performed on 12/27/2023 (hh) Patient # 33 testing performed on 12/28/2023 (ii) Patient # 34 testing performed on 12 /29/2023 (jj) Patient # 35 testing performed on 12/29/2023 (kk) Patient # 36 testing performed on 01/08/2024 (ll) Patient # 37 testing performed on 01/12/2024 (mm) Patient # 38 testing performed on 01/17/2024 (nn) Patient # 39 testing performed on 01/19/2024 (oo) Patient # 40 testing performed on 01/29/2024 (pp) Patient # 41 testing performed on 02/05/2024 (qq) Patient # 42 testing performed on 02/07/2024 (rr) Patient # 43 testing performed on 02/12/2024 (ss) Patient # 44 testing performed on 02/15/2024 (tt) Patient # 45 testing performed on 02/26/2024 (uu) Patient # 46 testing performed on 03/04/2024 (vv) Patient # 47 testing performed on 03/15/2024 (ww) Patient # 48 testing performed on 03/19/2024 (xx) Patient # 49 testing performed on 04/08/2024 (yy) Patient # 50 testing performed on 04/17/2024 (zz) Patient # 51 testing performed on 04/26/2024 (aaa) Patient # 52 testing performed on 06/18/2024
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with owner #1 and testing person #2, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed during the review period of January 2023 through June 2024. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to ensure quality control materials were not used beyond the expiration date. Refer to D5417; (b) The laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Medonic M-Series analyzer. Refer to D5429; (c) The laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for the testing performed using the Medonic M-Series analyzer. Refer to D5441.
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 owner #1 and testing person #2, the laboratory failed to ensure patient test reports included the name, as stated on the CLIA certificate, address of the laboratory location where the testing was performed, unique patient identifier, and normal patient reference ranges for two of two reports reviewed. Findings include: (1) On 07/11/2024 at 12:45 pm, testing person #2 stated CBC (Complete Blood Count) testing was performed using the Medonic M-Series analyzer; (2) A review of the following patient reports identified the laboratory name, as stated on the CLIA certificate, address of the laboratory location where testing was performed, unique patient identifier, and the normal patient reference ranges were not included: (a) Patient # 52 testing performed on 06/18/2024 (b) Patient # 53 testing performed on 07/10/2024 (3) The findings were reviewed with owner #1 and testing person #2, who stated on 07/11/2024 at 04:49 pm, the laboratory name and address, unique patient identifier, and reference ranges had not been included on the patient test reports.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.

	1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with office manager, owner #1, and testing person #2 the laboraory director failed to provide overall management and direction during the review period of January 2023 through June 2024. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results. Refer to D6014; (2) The laboratory director failed to ensure attestation statements had been signed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Refer to D6016; (3) The laboratory director failed to ensure that proficiency results were returned by the timeframe established by the proficiency program. Refer to D6017; (4) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (5) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (6) The laboratory director failed to ensure test reports included pertinent information required for interpretation. Refer to D6026.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #2, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results during the review period of January 2023 through June 2024. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Medonic M-Series analyzer. Refer to D5429.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #2, the laboratory

	director failed to ensure attestation statements had been signed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for five of five events. Findings include: (1) The laboratory director failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee and the analyst(s). Refer to D2015.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of records and interview with owner #1 and testing person #2, the laboratory director failed to ensure that proficiency results were returned by the timeframe established by the proficiency program for one of five events reviewed in 2023 and 2024. Findings include: (1) The laboratory director failed to ensure the laboratory participated in a proficiency testing event. Refer to D2123.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with owner #1 and testing person #2, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services during the review period of February 2023 through June 2024. Findings include: (1) The laboratory director failed to ensure quality control (QC) materials were not used beyond the expiration date. Refer to D5417; (2) The laboratory director failed to ensure the laboratory had control procedures to monitor the accuracy and precision of the complete analytic process. Refer to D5441.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with owner #1 and testing person #2 the laboratory director failed to ensure a quality assessment program had been established and maintained during the review period of January 2023 through June 2024. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on a review of records and interview with owner #1 and testing person #2, the laboratory director failed to ensure test reports included pertinent information required for interpretation for two of two patient reports. Findings include: (1) The laboratory director failed to ensure patient test reports included the name, as stated on the CLIA certificate, address of the laboratory location where the testing was performed, unique patient identifier, and normal patient reference ranges. Refer to D5805.