Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470685	03/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Midwest Medical Group, Pllc	8800 S E 15th Street, Midwest City, OK	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The survey was performed on 03/22,23/18. The surveyor reviewed the findings with the laboratory supervisor at the conclusion of the survey.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or 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 verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2016 and 2017 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) 2017 Hematology - First Event (i) MPV (Mean Corpuscular Volume) (aa) 1 of 5 HEM-02 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded result; (3) The surveyor asked the laboratory supervisor if the result had been documented as evaluated. The laboratory supervisor reviewed the records and stated the non-graded result had not been documented as reviewed.
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 written policies and procedures and interview with the laboratory supervisor, the laboratory failed to ensure policies and procedures had been approved, signed, and dated by the current laboratory director. Findings include: PROCEDURE MANUAL (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed using the Cell-Dyn Emerald analyzer; (2) The surveyor reviewed the procedure manual for the above testing. It had not been approved, signed, and dated by the current laboratory director; (3) The surveyor reviewed the procedure manual with the laboratory supervisor, who stated it had not been approved, signed, and dated by the current laboratory director. INDIVIDUALIZED QUALITY CONTROL PLAN (1) The laboratory supervisor stated the following to the surveyor: (a) The laboratory performed TSH (Thyroid Stimulating Hormone), FT4 (Free Thyroxine) and PSA (Prostate Specific Antigen) testing on the Qualigen FastPack analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP and identified the QCP (Quality Control Plan) portion had not been approved, signed, and dated by the current laboratory director; (3) The surveyor reviewed the records with the laboratory supervisor who stated the QCP had not been approved, signed, and dated by the current laboratory director.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to demonstrate performance specifications prior to patient testing. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor the laboratory performed TSH (Thyroid Stimulating Hormone), FT4 (Free Thyroxine) and PSA (Prostate Specific Antigen) testing on the Qualigen FastPack analyzer; (2) Later during the survey, the laboratory supervisor stated the following to the surveyor: (a) The analyzer was removed from service on 08/20/16; (b) The manufacturer sent a new analyzer back to the laboratory and it was put into service on 08/24/16. (3) The surveyor asked to review the performance specification records for the replacement analyzer. The laboratory supervisor stated that accuracy, precision, reportable ranges had not been demonstrated and reference ranges had not been verified on the new Qualigen FastPack analyzer.
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 supervisor, the laboratory failed to follow the manufacturer's quality control instructions. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated the following to the surveyor: (a) The Ace Alera analyzer was used to perform Albumin, Total Bilirubin, Direct Bilirubin, Calcium, CO2, Chloride, Creatinine, Glucose, ALP (Alkaline Phosphatase), Potassium, Total Protein, Sodium, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Triglycerides and BUN (Blood Urea Nitrogen); (b) Two levels of Alfa Wassermann Chemistry quality control (QC) materials were performed each day of patient testing. (2) Later on the first day, the surveyor reviewed the manufacturer's instructions for the QC materials which stated, "The value and expected range for each constituent are derived from intralaboratory data. The expected range includes instrument, reagent and environmental variations. The mean of several determinations may not duplicate the value printed on the package insert but should fall within the expected range. Each laboratory should establish its own mean and precision parameters."; (3) The surveyor reviewed records for testing performed from 03/01/18 through the first day of the survey. For each analyte (listed above), it was identified the laboratory had used the package insert ranges instead of laboratory established ranges for level 1(lot# 1213UNCM) and level 2 (lot# 937UECM) used during the review period; (4) The surveyor reviewed the findings with laboratory supervisor who stated the laboratory had used the package insert ranges instead of laboratory established ranges for determining acceptability of QC results.
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 the laboratory supervisor, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated the following to the surveyor: (a) The laboratory performed TSH (Thyroid Stimulating Hormone), FT4 (Free Thyroxine) and PSA (Prostate Specific Antigen) testing on the Qualigen FastPack analyzer; (b) IQCP's (Individualized Quality Control Plans) had been developed for the test systems. (2) The surveyor reviewed the IQCP (dated as effective 10/07/16). The surveyor then reviewed records for the testing. There was no evidence of QA reviews for the IQCP's between the effective date of 10 /07/16 and 03/28/18; (4) The surveyor reviewed the records with the director of laboratory services and asked if QA reviews had been performed in 2016, 2017 and 2018. The director of laboratory services stated QA reviews had not been performed.
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 ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed using Cell - Dyn Emerald analyzer; (2) On the second day of the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 03/22/18 at 10:08 am; the second report was for an adult male patient with the testing performed on 03/22/18 at 10:02 am. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit, which were: (a) RBC - 4.20 - 6.30 10^6/L (b) Hemoglobin - 12.0 - 18.0 g/dL (c) Hematocrit - 37 -51% (3) The surveyor viewed the findings with the laboratory supervisor who stated the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to ensure proficiency testing reports were reviewed. Findings include: (1) On the first day the survey, the surveyor reviewed 2016 and 2017 proficiency testing records. The Performance Evaluation for 1 of 24 events not been signed and dated as reviewed by the laboratory director: (a) Second 2016 Chemistry Group 2 Event (2) The surveyor reviewed the records with the laboratory supervisor, who stated the Performance Evaluation, as indicated above had not been signed and dated as reviewed by the laboratory director.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyor: (a) CBC (Complete Blood Count) was performed on the Cell-Dyn Emerald analyzer (b) TSH (Thyroid Stimulating Hormone), FT4 (Free Thyroxine), PSA (Prostate Specific Antigen) testing were performed on the Qualigen FastPack analyzer (c) Albumin, Total Bilirubin, Direct Bilirubin, Calcium, CO2, Chloride, Creatinine, Glucose, ALP (Alkaline Phosphatase), Potassium, Total Protein, Sodium, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Triglycerides and BUN (Blood Urea Nitrogen) testing were performed on the Ace Alera analyzer (d) Microscopic Urinalysis, Manual Differentials, Post Vasectomy (presence/absence), Wet Prep, and KOH Prep procedures were performed in the laboratory; (2) The surveyor reviewed personnel records for 2 persons who performed testing in 2016 and 2017 and identified the following: (a) Testing Person #1 (i) Although evaluations had been performed on 08/23/16 and 07/12/17, there was no evidence the person had been evaluated for performing Microscopic Urinalysis, Manual Differentials, Post Vasectomy (presence/absence), Wet Prep, and KOH Prep procedures. (b) Testing Person #2 (i) There was no evidence an annual evaluation had been documented as performed in 2016; (ii) Although an evaluation had been performed on 07/07/17, there was no evidence the person had been evaluated for performing Microscopic Urinalysis, Manual Differentials, Post Vasectomy (presence/absence), Wet Prep, and KOH Prep procedures. (3) The surveyor reviewed the findings with laboratory supervisor, who stated the Microscopic Urinalysis, Manual Differentials, Post Vasectomy (presence/absence), Wet Prep, and KOH Prep procedures were not included in the evaluations and an annual evaluation had not been documented as performed by the technical consultant in 2016 for testing person #2.