

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D0470685	<b>(X3) Date Survey Completed</b>  03/29/2022
<b>Name of Provider or Supplier</b>  Midwest Medical Group, Pllc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 03/28,29/2022 The findings were reviewed with the laboratory manager at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to following the manufacturer's instructions for specimen transport and storage for two of five patient specimens. Findings include: (1) On 03/28/2022 at 10:30 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed COVID-19 testing using the following instrument: (i) BD Veritor System - qualitative detection of SARS-CoV-2 nucleocapsid antigens from direct nasal swabs. (2) The surveyor reviewed the manufacturer's product insert titled, "BD Veritor System". Under the section titled, "Specimen Transport and Storage" which stated, "Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. It is essential that correct specimen collection and preparation methods be followed."; (3) The surveyor reviewed five test reports for patients tested on 03/14/2022 and 03/15/2022 and identified the following: (a) Patient Report #4 - Although the specimen result date and time were documented (03/14/2022 at 11:29 am), the collection date and time were not on the patient report; (b) Patient Report #5 - Although the specimen result date and time were documented (03/15/2022 at 12:06 pm), the collection date and time were not on the patient report; (4) The surveyor was not able to determine if the results had been interpreted within 1 hour after inoculation since the specimen</p>

collection date and time were not on the patient report; (5) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated on 03/28/2022 at 02:45 pm the laboratory could not prove the results had been interpreted within one hour after inoculation as indicated above.

**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 manager, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of 13 proficiency testing events reviewed. Findings include: (1) On 03/28/2022, the surveyor reviewed 2020 and 2021 proficiency testing records. The following was identified for one of 13 testing events: (a) Third 2020 Hematology Event for Urine Sediment - one of two result had not been graded by the proficiency testing program: (i) For the result (US-06), the following was identified: (aa) US-06 - Under "Expected Results" it stated, "See Data Summary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) The surveyor reviewed the record with the laboratory manager who stated on 03/28/2022 at 11:05 am, the laboratory had not evaluated the result that was not graded by the proficiency testing program.

**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 manager, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for Aspartate Aminotransferase and CO2 testing for two of two lot numbers. Findings include: (1) On 03/28/2022 at 10:20 am, the laboratory manager stated the following to the surveyor: (a) AST (Aspartate Aminotransferase) and CO2 testing were performed on the Alfa Wasserman ACE Axcel analyzer; (b) Two levels of Alfa Wasserman Chemistry QC (quality control)

materials (level 1 and level 2) were performed each day of patient testing; (c) Established ranges were used for determining acceptability of QC results. (2) The surveyor reviewed the Alfa Wasserman QC package insert instructions 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 that 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 QC records which included documentation of establishing QC ranges, Levey-Jennings graphs, and cumulative data for level 1 lot #1501UNCM and level 2 lot #1166UECM used during the review period of January 07, 2022 through the first day of the survey (03/28/2022). The documentation showed the ranges that had been utilized by the laboratory to determine acceptability of QC results for level 1 and level 2 were wider than the established QC ranges as follows: (a) AST (i) Level 1 - On 03/04/2022, the laboratory had changed the established mean and standard deviation (SD) to a mean of 49 and SD of 6.2 (range of 38.2 - 59.8), which was wider than the manufacturer's package insert range (range of 42.4 - 55.6). (b) CO2 (i) Level 1 - On 03/04/2022, the laboratory had changed the established mean and standard deviation (SD) to a mean of 13.6 and SD of 1.04 (range of 11.54 - 15.68), which was wider than the manufacturer's package insert range (range of 12.92 - 16.88); (ii) Level 2 - On 03/04/2022, the laboratory had changed the established mean and standard deviation (SD) to a mean of 26.0 and SD of 2.61 (range of 21.68 - 32.12), which was wider than the manufacturer's package insert range (range of 26.44 - 34.56). (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated on 03/29/2022 at 11:20 am, ranges wider than the manufacture's package insert range, as shown above, had been used to evaluate QC results.

**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 a patient report and interview with the laboratory manager, the laboratory failed to provide normal reference intervals for one of one wet prep patient test report. Findings include: (1) On 03/28/2022 at 10:10 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed wet prep testing. (2) The surveyor reviewed one test report for a patient tested on 03/28/2022 at 10:23 am. The report did not include a normal reference range; (3) The report was reviewed with the laboratory manager, who stated on 03/28/2022 at 02:30 pm the patient report did not include a normal reference range.