

|                                                                                                                            |                                                                                  |                                                     |
|----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------|
| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>37D0470685       | <b>(X3) Date Survey Completed</b><br><br>07/31/2026 |
| <b>Name of Provider or Supplier</b><br><br>Midwest Medical Group, Plc                                                      | <b>Street Address, City, State</b><br><br>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 recertification survey was performed on 07/30/2026 through 07/31/2026. Standard-level deficiencies were cited.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| D5401              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of policy, direct observation, and interview with the laboratory supervisor, the laboratory failed to follow their policy for specimen labeling for six of six patient blood samples observed. Findings include: 1. On 07/31/2026, a review of the policy titled, "Specimen Collection" stated, "Each tube must be labeled with the patient first name, and last name, date and time, and patient account number"; 2. Direct observation of the laboratory on 07/31/2026 at 01:45 pm, identified six patient tubes that had not been labeled with the date and time of collection; 3. Interview with the laboratory supervisor 07/31/2026 at 01:55 pm confirmed the laboratory failed to follow their policy for specimen labeling.</p> |
| D5429              | <p>MAINTENANCE AND FUNCTION CHECKS<br/>CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

Based on a review of records and interview with the laboratory supervisor, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Abbott Cell Dyn Emerald analyzer during the review period of January 2025 through the current date. Findings include: (1) On 07/30/2026 at 09:27 am, the laboratory supervisor stated the laboratory performed Complete Blood Count (CBC) using the Abbott Cell Dyn Emerald analyzer; (2) A review of the Abbott Cell-Dyn Emerald Operator's Manual, Appendix E "Sample Log and Work Sheets" required semi-annual piston lubrication; (3) A review of maintenance logs from January 2025 through the current date identified the semi-annual maintenance had not been documented as follows: (a) Between 06/19/2025 and 03/24/2026. (4) The records were reviewed with the laboratory supervisor manager who stated on 07/30/2026 at 01:05 pm, the maintenance procedures had not been documented as performed as stated 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.

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 have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for two of two analytes reviewed from March through June 2026 for the Qualigen FastPack IP System. Findings include: I. PROSTATE-SPECIFIC ANTIGEN (PSA) (1) On 07/30/2026 at 02:04 pm, the laboratory supervisor stated the following: (a) The laboratory performed Prostate-Specific Antigen (PSA) using the Qualigen FastPack IP System; (b) Two levels of Qualigen ControlKit Quality Control (QC) materials were performed weekly according to the IQCP; (c) Manufacturer's provided ranges were used for determining acceptability of QC results, which were specific to the FastPack Kit lot number being used; (d) Qualigen ControlKit QC level 1 lot #2601010 and QC level 2 Lot #2601011 had been put into use 03/10/2026 and were currently in use. (2) On 07/31/2026 at 11:44 am, a review of the QC records and manufacturer's provided QC ranges identified that the limits of acceptability had not been updated when the Fast Pack kit lot numbers had changed as follows: (a) FastPack Total PSA test kit lot 2602007 used from 04/22/2026 through 05/27/2026: (i) Laboratory QC ranges documented on the QC log sheet: (aa) Level 1 - 0.53 - 1.2 ng/mL (bb) Level 2 - 5.8 - 13.6 ng/mL (ii) Manufacturer's provided QC ranges: (aa) Level 1 - 0.56 - 1.3 ng/mL (bb) Level 2 - 6.0 - 13.9 ng/mL (b) FastPack Total PSA test kit lot 2602007 used from 05/29/2026 through 06/27/2026: (i) Laboratory QC ranges documented in the QC log sheet: (aa) Level 1 - 0.53 - 1.2 ng/mL (bb) Level 2 - 5.8 - 13.6 ng/mL (ii) Manufacturer's provided QC ranges: (aa) Level 1 - 0.56 - 1.3 ng/mL (bb) Level 2 - 6.0 - 13.9 ng/mL (c) FastPack Total PSA test kit lot 2604011 used from 06/28/2026 through 06/30

|              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              | <p>/2026: (i) Laboratory QC ranges documented in the QC log sheet: (aa) Level 1 - 0.53 - 1.2 ng/mL (bb) Level 2 - 5.8 - 13.6 ng/mL (ii) Manufacturer's provided QC ranges: (aa) Level 1 - 0.57 - 1.3 ng/mL (bb) Level 2 - 5.8 - 13.5 ng/mL (3) Interview with the laboratory supervisor on 07/31/2026 at 12:43 pm confirmed the QC ranges had not been updated when the Fast Pack kit lot numbers had changed. II. THYROID-STIMULATING HORMONE (TSH) (1) On 07/30/2026 at 02:04 pm, the laboratory supervisor stated the following: (a) The laboratory performed Thyroid-Stimulating Hormone (TSH) using the Qualigen FastPack IP System; (b) Two levels of Qualigen ControlKit Quality Control (QC) materials were performed weekly according to the IQCP; (c) Manufacturer's provided ranges were used for determining acceptability of QC results; (d) Qualigen ControlKit QC level 1 lot #2601010 and QC level 2 Lot #2601011 had been put into use 03/10/2026 and were currently in use. (2) On 07/31/2026 at 11:44 am, a review of the QC records and manufacturer's provided QC ranges identified that the limits of acceptability had not been updated when the Fast Pack kit lot numbers had changed as follows: (a) FastPack TSH test kit lot 2605016 used from 05/28/2026 through 06/30/2026: (i) Laboratory QC ranges documented in the QC log sheet: (aa) Level 1 - 0.45 - 1.5 mIU/L (bb) Level 2 - 14.1 - 30.1 mIU/L (ii) Manufacturer's provided QC ranges: (aa) Level 1 - 0.42 - 1.4 mIU/L (bb) Level 2 - 11.6 - 27.6 mIU/L (3) Interview with the laboratory supervisor on 07/31/2026 at 12:43 pm confirmed the QC ranges had not been updated when the Fast Pack kit lot numbers had changed.</p> |
| <b>D6018</b> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(e)(4)(iii)</p> <p>(e)(4)(iii) 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; and</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to ensure proficiency testing reports were reviewed and evaluated for one of five Hematology events reviewed in 2025 and 2026. Findings include: (1) A review of 2025 and 2026 Hematology proficiency testing events identified the "Performance Evaluations" included a space for the laboratory director or designee's signature and date (indicating review of the graded evaluation). The following was identified for one of five events reviewed: (a) API First event of 2025 - There was no evidence the Performance Evaluation had been signed and dated as reviewed by the laboratory director or designee. (2) The records were reviewed with the laboratory supervisor on 07/30/2026 at 10:55 am, who stated the graded evaluations had not been signed and dated as reviewed by the laboratory director or designee.</p>                                                                                                                                                                                                                                                                                                                                                                                                                      |