Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	41D0083228	03/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Midland Medical Assoc	315 Commonwealth Ave, Warwick, RI	

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	An onsite complaint survey was performed for compliance with 42 CFR Part 493, Requirements for Laboratories.
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 review of Sysmex XP-300 Analyzer 2021 Hematology proficiency testing (PT) records and staff interview, the laboratory failed to retain copies of American Proficiency Institute (API) PT result evaluations and PT submission documents. Findings include: 1. Record review on 03/16/2022 of CASPER Report D155 revealed scores of 100% for Hematology 2021 Events 1, 2, and 3. 2. Record review of 2021 API PT records on 03/16/2022 revealed no result evaluation documentation for API Hematology 2021 Events 1&3, and no attestation statements for API Hematology 2021 Events 1, 2, and 3. 3. Staff interview on 03/16/2022 with TP1 at 12:30 pm confirmed the findings above.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i)

	In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on record review of the FREND NanoEN Tek Analyzer User and Maintenance Manual records, lack of documentation, surveyor observation, and staff interview with the laboratory administrator (LA), the laboratory failed to maintain documentation of verification studies for the FREND NanoEN Tek Analyzer. Findings include: 1. Record review on 03/17/2022 of an Excel Spreadsheet, Midland Medical Medicare 84403 84153 84443 82306 1.1.21 to 9.21.21 listings CPT codes and patient testing service dates for Prostate Specific Antigen (PSA), Testosterone, 25-Hydroxyvitamin D (Vit D), and Thyroid Stimulating Hormone (TSH), revealed initial patient service dates of 03/21/2021 for Vit D, 04/15/2021 for PSA, 03/22/2021 for TSH, and 06/01 /2021 for Testosterone. 2. The LA stated during an interview on 03/16/2022 at 11:15 am that the FREND NanoEN Tek Analyzer performance verification studies were performed by the laboratory's technical consultant (TC) prior to patient testing, but the LA was unable to located the performance verification records. The LA further revealed that TC was off site, and she was unable to contact the TC to reveal where the records were located. 3. No performance verification records were found during the survey. 4. Surveyor observation on 03/16/2022 at 12:00 pm confirmed that the FREND NanoEN Tek Analyzer was unplugged, in a storage room, and not operational. 5. The laboratory performed 6 PSA, 56 Vitamin D, 55 TSH, and 1 Testosterone tests on the FREND NanoEN Tek Analyzer in 2021
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review of proficiency testing (PT) records for 2021 and staff interview with the laboratory administrator (LA), the laboratory failed to maintain PT testing, submission, and evaluation records for Prostate Specific Antigen (PSA), Testosterone, and 25-Hydroxyvitamin D (Vit D). Findings include: 1. Record review conducted on 03/16/2022 of PT API 2021 Chemistry Core PT records revealed a lack of PT testing, submission, and performance evaluation documentation for API 2021 Chemistry Core Events 1&2, and a lack of testing and performance evaluation for 2021 Chemistry Core Event 3. 2. Staff interview on 03/16/2022 at approximately 12: 45 pm with the LA confirmed the finding above. 3. Interview with the LA on 03/16 /2022 at 11:15 am further revealed that new TC was hired when the laboratory resumed testing operations late 2020 and was responsible for PT performed on the FREND NanoEN Tek Analyzer from January 2021 through November 2021. The LA further revealed that she was unable to contact the TC at this time. 4. Record review of a 01/07/2022 letter to COLA from the Laboratory Director revealed that the laboratory discontinued testing on the FREND NanoEN Tek Analyzer November 15, 2021. 5. The laboratory performed 6 PSA, 56 Vitamin D, 55 TSH, and 1 Testosterone tests on the FREND NanoEN Tek Analyzer in 2021.
D5400	ANALYTIC SYSTEMS

	CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of Sysmex XP-300 Automated Hematology Analyzer and NanoEnTek System 2021 records and staff interviews, the laboratory failed to have a FREND NanoEN Tek Analyzer procedure approved, signed and dated by the current laboratory director prior to use (refer to D5407); failed to monitor the correct storage temperature range for Sysmex XP-300 control samples (refer to D5413); failed to perform and document preventive maintenance according to the manufacturer instructions for the year 2021 for the XP-300 Automated Hematology Analyzer and FREND NanoEN Tek Analyzer (refer to D5429); failed to perform and document calibration verification for the Sysmex XP-300 Automated Hematology Analyzer (refer to D5439); failed to retain quality control (QC) Sysmex XP-300 instrument printouts for the year 2021(refer to D5481), and failed to document all corrective actions when temperatures were out of range (refer to D5781). The cumulative effect of these systematic problems resulted in the laboratory's inability to ensure the accuracy and reliability of Sysmex XP-300 and FREND NanoEN Tek Analyzer patient results reported in 2021.
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 record review and interview with the laboratory administrator (LA), the laboratory failed to have a FREND NanoEN Tek Analyzer procedure approved, signed and dated by the current laboratory director prior to use. Findings include: 1. Record review on 03/16/2022 of the FREND NanoEN Tek Analyzer User Manual revealed no signature by the current laboratory director prior to patient testing. The review further revealed that Prostate Specific Antigen (PSA), Testosterone, 25-Hydroxyvitamin D (Vit D), and Thyroid Stimulating Hormone (TSH) patient tests were performed on the FREND NanoEN Tek Analyzer. 2. Record review on 03/17 /2022 of an Excel Spreadsheet, Midland Medical Medicare 84403 84153 84443 82306 1.1.21 to 9.21.21 listings CPT codes and patient testing service dates for Prostate Specific Antigen (PSA), Testosterone, 25-Hydroxyvitamin D (Vit D), and Thyroid Stimulating Hormone (TSH), revealed initial patient service dates of 03/21/2021 for Vit D, 04/15/2021 for PSA, 03/22/2021 for TSH, and 06/01/2021 for Testosterone. 3. Record review of a 01/07/22 letter to COLA from the Laboratory Director revealed that the laboratory discontinued testing on the FREND NanoEN Tek Analyzer November 15, 2021. 4. Interview on 03/16/2022 with the LA at 1:45 pm confirmed the findings above.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the surveyor review of temperature records and interview with the testing personnel (TP1), the laboratory failed to monitor the correct storage temperature range for their Sysmex XP-300 blood control samples. Findings include: 1. Record review on 03/16/2022 of the 2021 temperature chart on the refrigerator that stored Sysmex XP-300 controls showed temperatures recorded in Fahrenheit. The temperature range was documented as 35.6F-48.6F, which is equivalent to 2 C-9 C. 2. Record review on 03/16/2022 of the Sysmex XP-300 Instructions for Use Manual, page 9-3, "Preparing control blood", states "Store at 2-8C, in upright position." 3. On 3/16/2022 at approximately 12pm, TP1 stated this was how the temperature has always been done and there was never a problem before.
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: A. Based on record review of 2021 preventive maintenance records and interview with testing personnel (TP1) and the laboratory administrator (LA), the laboratory failed to perform and document preventive maintenance according to the manufacturer instructions for the year 2021 for the XP-300 Automated Hematology Analyzer. Findings include: 1. Review conducted on 03/16/2022 of the Sysmex XP-300 Automated Hematology Analyzer records for the year 2021 revealed no preventive maintenance documentation for the year 2021. 2. Record review on 03/16/2022 of the Sysmex XP-300 Resource and Validation Manual, Document Number: LSS, Rev. 1, July 2013, Section 5 Maintence, stated, "Perform maintenance according to the maintenance schedule detailed in the XP-300 Instructions for Use, Chapter 12. Record the results on the maintenance log provided." 3. Interview with TP1 on 03/16/2022 at 11:24 am confirmed the findings above. 4. Interview with the LA on 03/16/2022 at 11:15 am revealed that the laboratory was not operational from the start of the COVID PHE through late Fall 2020. During this time no testing was performed on the Sysmex XP-300 Analyzer. The LA also revealed that the former technical consultant (TC) resigned in 2020 and a new TC was hired when the laboratory resumed testing operations late 2020. 5. Interview with the LA and TP1 at 11:46 am on 03/16/2022 revealed the laboratory ceased testing on the Sysmex XP-300 Automated Hematology Analyzer February 2022. B. Based on record review of 2021 preventive maintenance records and interview with testing personnel (TP1) and the

	laboratory administrator (LA), the laboratory failed to perform and document preventive maintenance according to the manufacturer instructions from January 2021 through November 2021 for the FREND NanoEN Tek Analyzer. Findings include: 1. Record review on 03/16/2022 of FREND System User Manual, Maintence revealed " FREND (Trademark) System checks to assure reliable and accurate test results, please check the following:" a) Check the signal input part of the FREND (Trademark) System once a month, regardless of the device use, using the Q.C. Cartridge and the Q. C. code chip to specifically test the optics. b) The FREND (Trademark) System checklist 1. Laser power 2. Laser alignment 3. Calculate ratio 2. Record review on 03 /16/2022 revealed no maintenance records for FREND NanoEN Tek Analyzer for the year 2021. 3. Interview with the TP1and the LA 03/16/2022 at 11:24 am confirmed the findings above. 4. Interview with the LA on 03/16/2022 at 11:15 am further revealed that new TC was hired when the laboratory resumed testing operations late 2020 and was responsible for testing performed on the FREND NanoEN Tek Analyzer from January 2021 through November 2021. The LA further revealed that she was unable to contact the TC at this time 5. The laboratory performed 6 PSA, 56 Vitamin D, 55 TSH, and 1 Testosterone tests on the FREND NanoEN Tek Analyzer in 2021.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based record review of calibration verification records and staff interview with the laboratory administrator (LA) and testing personnel (TP1), the laboratory failed to perform and document calibration verification for the Sysmex XP-300 Automated Hematology Analyzer. Findings include: 1. Record review conducted on 03/16/2022 of 2020 and 2021 calibration verification records for the Sysmex XP-300 Automated Hematology Analyzer revealed that calibration verification was performed on 09/02 /2020 and 07/14/2021. The record review revealed a lack of calibration verification documentation 6 months after the 09/02/2020 calibration verification check. 2. Interview with the LA on 03/17/2022 at 1:15 pm confirmed that the laboratory lacked

	calibration verification documentation for the 6-month period following the 09/02 /2020 calibration verification check. 3. Interview with the LA and TP1 at 11:46 am on 03/16/2022 revealed the laboratory ceased testing on the Sysmex XP-300 Automated Hematology Analyzer February 2022.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review of Sysmex XP-300 Automated Hematology Analyzer procedure and interview with the Laboratory Administrator (LA) and Testing Personnel (TP1) the laboratory failed to retain quality control (QC) instrument printouts for the year 2021. Findings include: 1. Record review conducted on 03/16 /2022 of the Sysmex XP-300 Automated Hematology Analyzer user manual stated QC Analysis is performed daily before running patient samples. 2. The surveyor requested Sysmex XP-300 Automated Hematology Analyzer QC printouts and records for the period of March 2, 2021 through July 14, 2021. 3. TP1 stated during an interview on 03/16/2022 at 1:40 pm that QC records were printed for 2021 for the Technical Consultant (TC) to review, but TP1 could not find the folder with the 2021 QC records. TP1 further stated she started the XP-300 Analyzer, but was unable to print the requested QC records from the instrument. 4. The LA and TP1 stated on 03 /16/2022 at 11:46 am that CBC testing on the Sysmex XP-300 Automated Hematology Analyzer ceased February 2022.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the surveyor review of temperature records and interview with the testing personnel (TP1), the laboratory failed to document all corrective actions when temperatures were out of range. Findings include: 1. Review of the temperature logs on 03/16/2022 for the year 2021 showed temperatures were out of range for 6 days in January, 2 days in February, 1 day in April, and 1 day in March. 2. During an interview with TP1 on 3/16/2022 at approximately 12 pm, TP1 stated they add water and monitor the fridge when the temperatures are out of range, but there was no documentation for this corrective action.

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 surveyor review of 2021 Sysmex XP-300 Automated Hematology Analyzer and NanoEnTek System records and staff interviews, the laboratory director failed to ensure the laboratory staff monitored the correct storage temperature range for Sysmex XP-300 control samples and performed preventive maintenance on the Sysmex XP-300 and FREND NanoEN TEK analyzers according to manufacturer instructions (refer to D6014); failed to ensure laboratory staff documented all corrective actions when temperatures were out of range for the storage of Sysmex XP-300 blood controls (refer to D6024), and failed to approve and sign the FREND NanoEN Tek Analyzer procedure director prior to use (refer D6031). The cumulative effect of these systematic problems resulted in the laboratory's inability to ensure the accuracy and reliability of Sysmex XP-300 and FREND NanoEN Tek Analyzer patient results reported in 2021.
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 record review and staff interview, the laboratory director failed to ensure laboratory staff monitored the correct storage temperature range for Sysmex XP-300 control samples, and peformed preventive maintenance on the Sysmex XP-300 and FREND NanoEN TEK analyzers according to manufacturer instructions (refer to D5413 and D5429).
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the laboratory director failed to ensure laboratory staff document all corrective actions when temperatures were out of range for the storage of Sysmex XP-300 blood controls (refer to D5781).
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to approve and sign the FREND NanoEN Tek Analyzer procedure director prior to use (refer to D5407).