Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0670151	09/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mid-South Internal Medicine Specialist Pc	7550 Wolf River Blvd Suite 102, Germantown, TN	

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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of calibration records, laboratory procedure manual, lack of procedures, manufacturer's instructions for use, manufacturer's operators manual, patient test reports, and staff interviews, the laboratory failed to have a procedure for the Tosoh G8 instrument that included calibration and calibration verification frequency requirements for the glycated hemoglobin A1c (Hgb A1c) analyte (Refer to D5403 Citation One), failed to have a procedure that included critical results for the Ortho Vitros 5600 instrument used for patient chemistry testing (Refer to D5403 Citation Two), failed to perform required calibrations following reagent lot number changes on the Ortho Vitros 5600 instrument (Refer to D5437), and failed to maintain compliance for the allegation of compliance submitted for the previous survey (08/07/2023) for calibration verifications on the Tosoh G8 instrument for the Hgb A1c analyte (Refer to D5439).
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 observation of the laboratory, review of the manufacturer's operator's manual, lack of records, laboratory procedures, and staff interviews, the laboratory failed to have a procedure for the Medonic M Series complete blood count (CBC) instrument that included flagged results for the automated white blood cell (WBC) differential (Refer to D5403 Citation Three), and failed to follow the established procedure and maintain compliance for the allegation of compliance submitted for the previous survey (08/07/2023) to compare results between the two Medonic M Series CBC instruments twice a year (Refer to D5775).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on laboratory observation, review of laboratory procedure manual, and staff interview, the laboratory failed to follow the procedure for labeling patient samples on the dates of the survey (09/23-09/24/2024). The findings include: 1. Observations of the laboratory on 09/23/2024 at 9:00 a.m. and 3:00 p.m. revealed patient blood samples that were collected and placed in the processing area in test tube racks. During the observation, testing persons one and two stated that nursing personnel collected patient blood samples and brought the tubes and test requisitions to the laboratory so that the testing personnel could place the electronic order, label patient tubes with a printed barcode, and perform testing. 2. A random selection of patient blood samples revealed the following for six of the six tubes reviewed: Patient 1: K2 EDTA used for CBC and Hgb A1c testing, and a Serum Separator tube used for chemistry testing labeled with the patient's first initial and last name only. Patient 2: K2 EDTA used for CBC and Hgb A1c testing, and a Serum Separator tube used for chemistry testing labeled with the patient's first initial and last name only. Patient 3: K2 EDTA used for CBC and Hgb A1c testing, and a Serum Separator tube used for chemistry testing labeled with the patient's full first and last name only. 3. A review of the laboratory procedure titled "Specimen Collection and Handling" in the section "Acceptable Samples" revealed that "Specimens must be properly labeled with the patient's complete name and secondary identifier, date and time of collection, and initial of a phlebotomist." 4. An interview with the laboratory director and testing persons one and two on 09/24/2024 at 11:00 a.m. confirmed the laboratory failed to follow the established procedure for specimen labeling. Word Key: K2 EDTA-dipotassium ethylenediaminetetraacetic acid
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Citation One Based on observation of the laboratory, review of calibration records, laboratory procedure manual, lack of procedure, and staff interviews, the laboratory failed to have a procedure for the Tosoh G8 instrument used for glycated hemoglobin A1c (Hgb A1c) patient testing that included calibration and calibration verification requirements. The findings include: 1. An observation of the laboratory on 09/23/2024 at 9:00 a.m. revealed the Tosoh G8 instrument (Serial #1611002) used for performing Hgb A1c patient testing. 2. A review of the laboratory Tosoh G8 calibration reports revealed that the testing personnel performed calibrations monthly. 3. A review of the Tosoh G8 Variant Analysis Mode Operator's Manual (used for the laboratory procedure) revealed that the manufacturer recommended weekly calibratrions but that the laboratory may establish a calibration interval based on quality control results. The operator's manual did not include calibration verification requirements. 4. The laboratory failed to provide a procedure that defined calibration and calibration verification requirements for the Hgb A1c analyte reported with the Tosoh G8 instrument. 5. An interview with the laboratory director and testing persons one and two on 09/24/2024 at 11:00 a.m. confirmed the laboratory failed to establish procedures for calibration and calibration verification requirements for the Hgb A1c analyte on the Tosoh G8 instrument. Citation Two Based on observation of the laboratory, review of laboratory procedure manuals, and staff interviews, the laboratory failed to have a procedure that defined critical results for tests performed on the Ortho Vitros 5600 chemistry instrument. The findings include: 1. Observation of the laboratory on 09/23/2024 at 9:00 a.m. revealed the Ortho Vitros 5600 (Serial 56004860) used for patient chemistry testing. 2. A review of the laboratory procedure manual revealed no list of panic/life threatening values or procedures to follow when panic values were obtained for tests performed on the Ortho Vitros 5600 instrument. 3. An interview with the laboratory director and testing persons one and two on 09/24 /2024 at 11:00 a.m. revealed the following statements: The tests with critical values are flagged in the laboratory information system for actions. The laboratory did not have a written procedure that defined critical values. This confirmed the survey findings. Citation Three Based on observation of the laboratory, review of the operator's manual, lack of records, and staff interviews, the laboratory failed to have a procedure for the Medonic M Series complete blood count (CBC) instrument used for patient testing that included flagged results for the automated white blood cell (WBC) differential. The findings include: 1. Observation of the laboratory on 09/23/2024 at 9: 00 a.m. revealed a Medonic M Series instrument in Suite A (Serial 29629) and on 09 /24/2024 at 10:25 a.m. a second Medonic M Series instrument in Suite B (Serial 47661) used for patient CBC testing. 2. A review of the Medonic M Series operator's manual section "Interpretation of Results" revealed the following: Instrument flags

	(BD, NM, OM, and TM) for WBC differential abnormalities. "Performing a slide review (which is recommended by the manufacturer) or refferring the specimen for further study when flags are attached to the differential WBC is left to discretion of the ordering provider.". 3. The laboratory did not have a procedure for testing personnel to follow when the Medonic instrument flagged WBC differential results on the survey date (09/24/2024). 4. An interview with the laboratory director and testing persons one and two on 09/24/2024 at 11:00 a.m. confirmed that the laboratory did not have a procedure for testing personnel to follow when patient results were flagged by the Medonic CBC instrument.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer's instructions for use, lack of records, and staff interview, the laboratory failed to perform required calibrations following reagent lot number changes on the Ortho Vitros 5600 instrument used for patient chemistry testing in 2023 and 2024. The findings include: 1. Observation of the laboratory on 09/23/2024 at 9:00 a.m. revealed the Ortho Vitros 5600 (Serial 56004860) used for patient chemistry testing. Reagents used included sodium (Na), potassium (K), chloride (Cl), and electrolyte reference fluid (ERF). During the observation, testing persons one and two described the calibration procedures for the Ortho Vitros 5600 and stated that the testing personnel did not perform calibrations after ERF reagent lot changes. 2. A review of the manufacturer's instructions for the use for the ERF reagent revealed that the Na, K, and Cl analytes required a calibration following a lot number change of the ERF reagent. 3. Documentation for calibration of analytes following ERF reagent lot changes was not available on the survey date (09/24/2024). 4. An interview with the laboratory director and testing persons one and two on 09/24/2024 at 11:00 a.m. confirmed the survey findings.
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 on observation of the laboratory, review of the manufacturer's operator manual, laboratory records, lack of records, patient test reports, and staff interviews, the laboratory failed to perform calibration verification for the glycated hemoglobin A1c (Hgb A1c) analyte on the Tosoh G8 instrument in 2024. This deficiency was cited at the previous survey (08/07/2023), and the laboratory failed to maintain compliance. The findings include: 1. An observation of the laboratory on 09/23/2024 at 9:00 a.m. revealed the Tosoh G8 instrument (Serial #1611002) used for performing Hgb A1c patient testing. 2. A review of the manufacturer's operator's manual revealed, "The Tosoh Automated Glucohemoglobin analyzer HLC-723G8 has a two-point automatic calibration function for stable HbA1c (SA1c)." 3. A review of the laboratory's records revealed a calibration verification performed on 09/08/2023. There was no documentation that the calibration verification had been performed since 09/08/2023. 4. A review of patient test records revealed the following patient test reports for Hgb A1c: Patient 18137 on 03/08/2024 Patient 19739 on 06/12/2024 Patient 12949 on 08 /01/2024 Patient 7261 on 08/19/2024 5. An interview with the laboratory director and testing persons one and two on 09/24/2024 at 11:00 a.m. confirmed that the laboratory failed to perform the calibration verification for the Hgb A1c at least every six months in 2024.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure, lack of records, and staff interviews, the laboratory failed to follow the established procedure to compare results between the two Medonic M series complete blood count (CBC) instruments twice a year in 2023 and 2024. This deficiency was cited at the previous survey (08/07/2023), and the laboratory failed to maintain compliance. The findings include: 1. Observation of the laboratory on 09/23/2024 at 9:00 a.m. revealed a Medonic M Series CBC instrument used for patient CBC testing in Suite A (Serial 29629) and a second Medonic CBC instrument on 09/24/2024 at 10:25 a.m. in Suite B

	(Serial 47661) . 2. A review of the procedure titled "Method Comparisons between Medonic M Series CBC instruments "A" and "B" at Midsouth Internal Medicine" provided for the previous survey (08/07/2023) allegation of compliance revealed that the laboratory personnel would perform comparison studies using the American Proficiency Institute (API) proficiency testing (PT) samples after the events were closed. The technical consultant would then evaluate the results. 3. Instrument comparison records for the Medonic M Series instruments were unavailable on the survey date, 09/24/2024. 4. An interview on 09/24/2024 at 11:00 a.m. with the laboratory director and testing persons one and two confirmed the laboratory performed CBC patient testing from both Medonic M Series instruments in 2023 and 2024 and failed to follow the procedure and maintain compliance for instrument comparisons in 2023 and 2024.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), Aspen Web 116 database, Laboratory Personnel Report (CLIA) (Form CMS-209), lack of documentation, and staff interviews the laboratory director failed to maintain compliance with the requirements at 493.51 which requires notification of a change in laboratory director within 30 days of the change. The findings include: 1. A review of Form CMS-116 and Form CMS-209 revealed that the laboratory director listed did not match the director of record in the Aspen Web 116 database. 2. The laboratory failed to provide evidence that the state agency had been notified of the change within 30 days. 3. An interview with the laboratory director on 09/24/2024 at 11:00 a.m. confirmed that the laboratory director position changed in June 2024, and the laboratory director failed to notify the state agency within 30 days of the change.