Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2153895	07/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Midwest Institute For Minimally Invasive Therapies	2415 S Michigan Ave, Chicago, IL	

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 direct observation, review of the CMS-209 (Laboratory Personnel Report), laboratory policies and procedures, Individual Quality Control Plan (IQCP), laboratory records, lack of documentation, and interviews with the technical consultant (TC); the laboratory failed to have a competency assessment policy and procedure in place to assess employee competency for one of one TC (See D5209), failed to have policy and procedure manuals reviewed, approved, signed, and dated by the current laboratory director (See D5407), failed to have IQCP's for three of three cartridge types utilized on the i-Stat analyzer (See D5445a) and failed to perform quality control procedures as specified by the i-Stat IQCP for one of two hematology tests performed on the i-Stat analyzer (See D5445b), failed to include all the required components of a laboratory test report, including the facility's address, on eight of eight patient test reports (See D5805), and failed to have pertinent reference ranges correlate between the i-Stat analyzer's standard operating procedure and patient test reports (See D5807).
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 direct observation, review of the CMS-209 (Laboratory Personnel Report), laboratory policies and procedures, Individual Quality Control Plan (IQCP), laboratory records, lack of documentation, and interviews with the technical consultant (TC); the laboratory failed to have a competency assessment policy and procedure in place to assess employee competency for one of one TC (See D5209), failed to have policy and procedure manuals reviewed, approved, signed, and dated by the current laboratory director (See D5407), failed to have IQCP's for three of three cartridge types utilized on the i-Stat analyzer (See D5445a) and failed to perform quality control procedures as specified by the i-Stat IQCP for one of two hematology tests performed on the i-Stat analyzer (See D5445b), failed to include all the required components of a laboratory test report, including the facility's address, on eight of eight patient test reports (See D5805), and failed to have pertinent reference ranges correlate between the i-Stat analyzer's standard operating procedure and patient test reports (See D5807).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report), laboratory policies and procedures, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to have a competency assessment policy and procedure in place to assess employee competency for one of one technical consultant. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) revealed one technical consultant. 2. Review of laboratory policies and procedures revealed the laboratory lacked a competency assessment policy and procedure to assess the competency of one of one TC. 3. Interview with the TC on 07/24/2025, at 9:41 am, confirmed the laboratory failed to have a competency assessment policy and procedure in place to assess employee competency for one of one technical consultant.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 review of laboratory policies and procedures, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to have one of one i-Stat policy and procedure manual reviewed, approved, signed, and dated by the current laboratory director (as noted on the CMS-209 Laboratory Personnel Report) for the specialties of chemistry and hematology. Findings include: 1. Review of laboratory policy and procedure manuals revealed no laboratory director (LD) approval, including signature and date, by the current LD for the procedure, "i-Stat 1"

	used for Chem-8+, Protime, and Activated Clotting Time testing. 2. Interview with the laboratory representative on 07/24/2025, at 11:04 am, confirmed the LD had not signed or dated the procedure relating to chemistry and hematology testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: a) Based on direct observation, review of the laboratory's policies and procedures, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to have IQCP's for three of three cartridge types utilized on the i-Stat analyzer in the specialties of chemistry and hematology. Findings include: 1. Direct observation upon a tour of the laboratory on 07/24/2025, at 9:45 am, revealed three cartridge types utilized for patient testing on the i-Stat analyzer (Serial Number: 401381). a) Chem 8+ cartridges utilized for chemistry (sodium, potassium, chloride, calcium, glucose, blood urea nitrogen, and creatinine) and hematology (Hematocrit) testing; b) Activated Clotting Time (ACT) cartridges utilized for hematology testing; and c) Protime / International Normalized Ratio (PT/INR) cartridges utilized for hematology testing. 2. Review of the laboratory's policies and procedures for i-Stat testing revealed a lack of IQCP's for each of the individual cartridge types that performed patient testing. 3. Interview with the TC on 07/24/2025, at 9:53 am, confirmed the laboratory failed to have IQCP's for three of three cartridge types utilized on the i-Stat analyzer in the specialties of chemistry and hematology. b) Based on review of the laboratory's Individual Quality Control Plan (IQCP) for the i-Stat analyzer, laboratory records, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to perform quality control (QC) procedures as specified by the i-Stat IQCP for one of two Protime/International Normalized Ratio (PT/INR) tests performed on the i-Stat analyzer in the years of 2023 through 2025 in the specialty of hematology. Findings include: 1. Review of the laboratory's IQCP for the i-Stat analyzer (Serial Number: 401381), utilized for PT/INR testing, stated, under "Liquid QC", "1. Frequency: All new shipments will be QC'd upon arrival with 2 levels of controls and monthly." 2. Review of laboratory records revealed one of two patients tested for PT/INR in the years of 2023 through 2025 failed to have PT/INR controls performed within one month prior of patient testing. Patient: 1954 Date of testing: 02/12/2024 Date QC performed: 12/27/2023 3. Interview with the TC on 07/24 /2025, at 1:00 pm, confirmed the laboratory failed to perform QC procedures as specified by the IQCP for one of two PT/INR tests performed on the i-Stat analyzer in the years of 2023 through 2025 in the specialty of hematology.
D5805	TEST REPORT CFR(s): 493.1291(c)

	(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to include all the required components of a laboratory test report, including the facility's address, for six of six i-Stat Chem 8+ and two of two i-Stat Protime / International Normalized Ratio (PT/INR) test reports reviewed from 2023 through the date of survey, 07/24/2025. Findings include: 1. Review of six of six i-Stat Chem 8+ patient test reports found the laboratory failed to indicate the testing facility's address on the laboratory's patient test report. Patient: Date of Testing: 2755 07/31/2023 3127 11/13/2023 3858 04/29/2024 5480 11/01/2024 5238 01/27/2025 6618 06/09/2025 2. Review of two of two i-Stat PT/INR patient test reports found the laboratory failed to indicate the testing facility's address on the laboratory's patient test report. Patient: Date of Testing: 1956 10/09/2023 1954 02/12/2024 3. Interview with the TC on 07/24/2025, at 1:00 pm, confirmed the laboratory failed to include all the required components of a laboratory test report, including the facility's address, for six of six i-Stat Chem 8+ and two of two i-Stat PT/INR test reports reviewed from 2023 through the date of survey, 07/24/2025.
D5807	TEST REPORT CFR(s): 493.1291(d) (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 review of laboratory policies and procedures, patient test reports, and interview with the technical consultant (TC); the laboratory failed to have pertinent reference ranges correlate between the i-Stat analyzer's standard operating procedure (SOP) and patient test reports, including six of six Chem 8+ patient test reports and two of two Protime/International Normalized Ratio (PT/INR) patient test reports, in the specialties of chemistry and hematology. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Procedure Manual for the i-Stat System", which stated the following reference ranges for the analytes of the Chem 8+ cartridge: Analyte: Reference Range: Sodium 135 - 145 mmol/L** Potassium 3.5 - 5.0 mmol/L Chloride 100 - 109 mmol/L Calcium 1.12 - 1.32 mmol/L Glucose 70 - 105 mg/dL*** BUN* 6 - 20 mg/dL Creatinine 0.5 - 1.1 mg/dL Hematocrit Female: 34 - 47 %PCV**** Male: 40 - 52 %PCV *BUN = Blood Urea Nitrogen **mmol/L = millimoles per liter ***mg/dL - milligrams per deciliter ****% PCV = % packed cell volume 2. Review of laboratory policies and procedures revealed the procedure titled "Procedure Manual for the i-Stat System", which failed to provide a reference range for the results of the PT/INR cartridge. 3. Review of laboratory policies and procedures revealed the procedure titled "Procedure Manual

	for the i-Stat System" failed to be reviewed, approved, signed, and dated by the current laboratory director (as noted on the CMS-209 Laboratory Personnel Report) for the specialties of chemistry and hematology (See D5407). 4. Review of six of six i-Stat Chem 8+ patient test reports (2755, 3127, 3858, 5238, 5480, and 6618) revealed the following reference ranges for the analytes of the Chem 8+ cartridges: Analyte: Reference Range: Sodium 138 - 146 mmol/L Potassium 3.5 - 4.9 mmol/L Chloride 98 - 109 mmol/L Calcium 1.2 - 1.32 mmol/L Glucose 70 - 105 mg/dL BUN 8 - 26 mg/dL Creatinine 0.6 - 1.3 mg/dL Hematocrit Female: 38 - 46 %PCV Male: 43 - 51 %PCV 5. Review of two of two i-Stat PT/INR patient test reports (1954 and 1956) revealed the following reference ranges for the analytes of the PT/INR cartridges: Analyte: Reference Range: PT 11 to 13.5 seconds INR 0.8 - 1.1 6. Interview with the TC on 07 /24/2025, at 11:04 am, confirmed the laboratory failed to have pertinent reference ranges correlate between the i-Stat analyzer's SOP and patient test reports, including six of six Chem 8+ patient test reports and two of two PT/INR patient test reports, in the specialties of chemistry and hematology.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, patient test reports, and interview with the technical consultant (TC); the laboratory director failed to ensure all the required components of a laboratory test report, including the facility's address, were present on eight of eight patient test reports reviewed (See D5805) and failed to ensure pertinent reference ranges correlate between the i-Stat analyzer's standard operating procedure and patient test reports (See D5807) and in the specialties of chemistry and hematology.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation, and interview with the technical consultant (TC); the laboratory director failed to ensure policy and procedure manuals were reviewed, approved, signed, and dated by the current laboratory director (as noted on the CMS-209 Laboratory Personnel Report) for the specialties of chemistry and hematology (See D5407).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test

	results; This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's Individual Quality Control Plan (IQCP), lack of documentation, and interview with the technical consultant (TC); the TC failed to ensure IQCP's were available for three of three cartridge types utilized on the i-Stat analyzer and failed to ensure quality control procedures were performed as specified by the i-Stat IQCP in the specialties of chemistry and hematology (See D5445a and D5445b).