

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2153895	(X3) Date Survey Completed 07/16/2021
Name of Provider or Supplier Midwest Institute For Minimally Invasive Therapies	Street Address, City, State 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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record and manual review, manufacturer's instructions, and interview with the technical consultant (TC), the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 for performing Chemistry and Hematology testing in the laboratory. Findings Include: 1. The laboratory failed to meet the following analytic systems requirements: *Failed to establish manufacturer's performance specifications for Routine Chemistry testing. See D5421. *Failed to follow manufacturer's requirements and perform function checks necessary for accurate and reliable test results and test result reporting. D5431. *Failed to establish control procedures for Routine Chemistry testing. See D5441. *Failed to perform control procedures for Hematology testing. See D5445.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)</p>

Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review, the Food and Drug Administration (FDA), and interview with the technical consultant (TC), the laboratory failed to demonstrate that it could obtain performance specifications comparable to those established by the manufacturer before reporting patient test results in the subspecialty of Routine Chemistry, affecting 20 patients. Findings: 1. The Abbott i-STAT operator's and procedures manual, FDA website, quality control (QC) documents, and patients test results were reviewed. 2. The laboratory used the i-STAT handheld analyzer CHEM8+ test system for Routine Chemistry testing of the following analytes: Sodium (Na); Potassium (K); Calcium (Ca); Chloride (Cl); Creatine (Crea); Glucose (Glu); and Urea (BUN) in the surgery center laboratory. 3. The FDA changed the categorization of the i-STAT CHEM8+ test system from "Waived" to "Moderate" on 02/07/2020 for the testing of the analytes listed in findings #2. 4. The manufacturer's instructions were provided for verifying the reportable range of the analytes in the CHEM8+ panel by performing calibration verification. 5. The laboratory failed to perform the calibration procedure to ensure the i-STAT analyzer met the manufacturer's specification for Routine Chemistry testing, prior to testing patients. 6. The laboratory reported 20 patient test result during the time period of 02/07/2020 through 07/16/2021. 7. On a Recertification survey conducted on 07/16/2021 at 3:45 PM, the TC confirmed the above findings.

D5431

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on record review and interview with the technical consultant (TC); the laboratory failed to perform and document the maintenance protocols as defined by the manufacturer with at least the frequency specified by the manufacturer, to ensure equipment, instrument, and test system performances are accurate and reliable, affecting 40 patients. Findings: 1. The Abbott i-STAT manufacturer's manual, maintenance documents, and the laboratory individual quality control plan (IQCP) were reviewed. 2. The laboratory used the Abbott i-STAT analyzer to test for the following analytes: *Activated Clotting Time - Celite (ACT-C), *Protime /International Normalized Ratio (PT/INR); *Sodium (Na); *Potassium (K); *Calcium (Ca); . *Chloride (Cl); *Creatine (Crea); *Glucose (Glu); and *Urea (BUN) in the surgery center. 2. The manufacturer's instructions in Section 14: Quality Control (QC) states " Check each Handheld reader with the Electronic Simulator, using either the internal or external simulator, once on each day of use.". 3. The patients' results log book showed patient tests were performed 36 day during the period of 09/30/2019 through 07/15/2021. 4. The i-STAT System: Electronic Simulator log revealed the following documented test dates: 06/12/2019; 12/20/2019; 08/27/2020; and 12/01 /2020; and 07/16/2021. 5. Further review of the log revealed the Electronic Simulator check of either internal or external or both were not performed for 36 out of 36 days

patients were tested. 6. The laboratory failed to follow its IQCP to perform and document the electronic check each day of testing. 7. On a Recertification survey conducted on 07/16/2021 at 3:45 PM, the TC confirmed the above findings.

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 record review, the Food and Drug Administration (FDA), lack of documentation, and interview with the technical consultant (TC), the laboratory failed to establish control procedures that monitor the accuracy and precision of the complete analytic process for testing performed in the subspecialty of Routine Chemistry, affecting 20 patients. Findings: 1. The i-STAT operator's and procedures manual, quality control (QC) logs and data sheets, and patients' results were reviewed. 2. The laboratory used the i-STAT handheld analyzer CHEM8+ test system for Routine Chemistry testing of the following analytes: Sodium (Na); Potassium (K); Calcium (Ca); Chloride (Cl); Creatine (Crea); Glucose (Glu); and Urea (BUN) in the surgery center laboratory. 3. The FDA changed the categorization of the i-STAT CHEM8+ test system from "Waived" to "Moderate" on 02/07/2020 for the testing of the analytes listed in findings #2. 4. Review of the laboratory manual, QC documents and patients' results revealed the following: *The laboratory failed to establish quality control procedures when the CHEM8+ test system complexity was changed to moderate. *The CHEM8+ tests were performed 17 days during the period of 02/07/2020 through 07/15/2021. *The laboratory failed to perform electronic QC check procedures and test 2 levels of control material each day of patient testing for 16 out of 17 test dates. *Twenty (20) patients were tested since 02/07/2020. 5. The laboratory failed to establish and implement QC procedures for Routing Chemistry testing when the i-STAT test system's level of complexity changed, prior to testing patients. 6. On a Recertification survey conducted on 07/16/2021 at 3:45 PM, the TC confirmed the above findings.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

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. (g) The

laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review, manufacturer's instructions, and interview with the technical consultant (TC); the laboratory failed to perform control procedures using the number and frequency established by the laboratory for Hematology, affecting 18 out of 18 patients. Findings Include: 1. The laboratory's individual quality control plan (IQCP), the manufacturer's instructions, quality control (QC) logs from the month of October of 2019 through July of 2021, and patient test printout results were reviewed. 2. The laboratory used the Abbott i-STAT analyzer to test for Activated Clotting Time - Celite (ACT-C) and Protime/International Normalized Ratio (PT/INR) in the surgery center. 3. The ACT-C and PT/INR IQCP revealed the following: *The laboratory must document and perform two levels of controls monthly and with each new shipment. *The laboratory must perform and document the electronic function checks each day of use. 4. Review of the QC, manual, and maintenance logs showed the laboratory failed to print the i-Stat manual for their analyzer, failed to perform and document monthly QC procedures for 8 out 21 months; and failed to perform and document electronic function checks each day of use for 36 out of 36 test dates. 5. The Quality Assessment (QA) plan failed to ensure that QC procedures were followed by testing personnel, and failed to monitor, assess, and when indicated, make adjustments when needed, due to changes in the manufacturer's instructions or the laboratory's QC plan. 6. The laboratory failed to establish and follow an IQCP that ensures the i-STAT test system performances are accurate and reliable for Hematology testing and in accordance to the manufacturer's instructions. 7. On a Recertification survey conducted on 07/16/2021 at 3:45 PM, the TC confirmed the above findings.

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 record review and interview with the technical consultant (TC); the laboratory failed to ensure reference ranges or normal values are included in the final test report, affecting 8 out of 8 patients. Findings: 1. The patients' final report of 8 randomly selected patients were reviewed. 2. The laboratory failed to include the "reference intervals" or "normal" values for the following reported analytes: *Activated Clotting Time - Celite (ACT-C), *Protime/International Normalized Ratio (PT/INR); *Sodium (Na); *Potassium (K); *Calcium (Ca); . *Chloride (Cl); *Creatine (Crea); *Glucose (Glu); and *Urea (BUN). 3. On a Recertification survey conducted on 07/16/2021 at 3:45 PM, the TC confirmed the above findings.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on record review and an interview with the technical consultant (TC), the laboratory failed to ensure individuals meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the complexity of tests performed in the specialties of Hematology and Chemistry for 1 out of 5 testing personnel (TP). Findings: 1. The laboratory failed to ensure that laboratory personnel meet the education requirement for moderately complex testing, prior to testing patients. See D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on record review, the Laboratory Personnel Report (CMS-209) and interview with the technical consultant (TC); the laboratory failed to ensure laboratory employees meet the qualification requirements for performing moderately complex testing in the specialty of Hematology and Chemistry for 1 out of 4 testing personnel (TP). Findings: 1. The CMS 209, employee files, and manuals were reviewed. 2. The CMS 209 lists 4 TP (TP1, TP2, TP3, and TP4) performing Hematology and Routine Chemistry tests. 3. The personnel education credentials revealed that TP3 had education documentation from a foreign country. These documents had not been evaluated for United States equivalency. 4. The laboratory failed to ensure the foreign documents of TP3 met the education requirements for moderately complex testing, prior to testing patients. 5. On a Recertification survey conducted on 07/16/2021 at 3:45 PM, the TC confirmed the above findings.