Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2153895	11/06/2024
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to participate in the API Core Chemistry PT events two and three of 2024 (See D2089 and D2123); the laboratory failed to successfully participate in PT for the subspeciality of routine chemistry (See D2097) and the routine chemistry analytes Chloride (Cl, Analyte #0355), Creatinine (Analyte # 0405), Glucose (Analyte #0415), Potassium (K, Analyte #0465), Sodium (Na, Analyte #0475), and Blood Urea Nitrogen (BUN, Analyte #0505) (See D2096) during PT events two and three of 2024; and the

	laboratory failed to successfully participate in PT for the specialty of hematology (See D2131) and the hematology analytes Hematocrit (HCT, Analyte #0785) and Hemoglobin (HGB, Analyte #0795) (See D2130) during PT events two and three of 2024.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to participate in the API Core Chemistry PT events two and three of 2024 for the routine chemistry analytes Calcium, Ionized (non-regulated), Chloride (Cl), Creatinine, Glucose, Potassium (K), Sodium (Na), and Blood Urea Nitrogen (BUN). Findings Include: 1. Review of the CASPER Report 0155D, ran on 11-01-2024, identified the 0% scores for the regulated chemistry analytes Chloride (Cl), Creatinine, Glucose, Potassium (K), Sodium (Na), and Blood Urea Nitrogen (BUN) in events two and three of 2024. 2. Review of API Core Chemistry PT event summaries confirmed the laboratory failed to participate, resulting in a score of 0% for Calcium, Ionized (non-regulated), Chloride (Cl), Creatinine, Glucose, Potassium (K), Sodium (Na), and Blood Urea Nitrogen (BUN) in PT events two and three of 2024.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to successfully participate PT for the routine chemistry analytes Chloride (Cl, Analyte #0355), Creatinine (Analyte # 0405), Glucose (Analyte #0415), Potassium (K, Analyte #0465), Sodium (Na, Analyte #0475), and Blood Urea Nitrogen (BUN, Analyte #0505) during events two and three of 2024, resulting in the initial unsuccessful PT performance. Findings Include: 1. Review of the CASPER Report 0155D, ran on 11-01-2024, identified the initial unsuccessful PT performance for the routine chemistry analytes: Chloride (Cl, Analyte #0355), Creatinine (Analyte # 0405), Glucose

	(Analyte #0415), Potassium (K, Analyte #0465), Sodium (Na, Analyte #0475), and Blood Urea Nitrogen (BUN, Analyte #0505). ROUTINE CHEMISTRY Cl - EVENT-2, 2024 = 0% - Unsatisfactory Cl - EVENT-3, 2024 = 0% - Unsatisfactory Creatinine - EVENT-2, 2024 = 0% - Unsatisfactory Creatinine - EVENT-3, 2024 = 0% - Unsatisfactory K - EVENT-2, 2024 = 0% - Unsatisfactory K - EVENT-3, 2024 = 0% - Unsatisfactory Na - EVENT-2, 2024 = 0% - Unsatisfactory Na - EVENT-3, 2024 = 0% - Unsatisfactory BUN - EVENT-2, 2024 = 0% - Unsatisfactory BUN - EVENT-3, 2024 = 0% - Unsatisfactory 2. Review of API Core Chemistry PT event summaries confirmed the laboratory failed to participate, resulting in a score of 0% for Cl, Creatinine, Glucose, K, Na, and BUN in PT events two and three of 2024.
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to successfully participate PT for the subspecialty of routine chemistry (Analyte #0245) during events two and three of 2024, resulting in the initial unsuccessful PT performance for the subspecialty. Findings Include: 1. Review of the CASPER Report 0155D, ran on 11-01-2024, identified the initial unsuccessful PT performance for the subspecialty of routine chemistry. CHEMISTRY Routine Chemistry - EVENT-2, 2024 = 0% - Unsatisfactory Routine Chemistry - EVENT-3, 2024 = 0% - Unsatisfactory 2. Review of API Core Chemistry PT event summaries confirmed the laboratory failed to participate, resulting in a score of 0% for the subspecialty of Routine Chemistry in PT events two and three of 2024.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to participate in the API Core Chemistry PT events two and three of 2024 for the hematology analytes Hematocrit (HCT) and Hemoglobin (HGB). Findings Include: 1. Review of the

	CASPER Report 0155D, ran on 11-01-2024, identified the 0% scores for the regulated hematology analytes Hematocrit (HCT) and Hemoglobin (HGB) in events two and three of 2024. 2. Review of API Core Chemistry PT event summaries confirmed the laboratory failed to participate, resulting in a score of 0% for Hematocrit (HCT) and Hemoglobin (HGB) in PT events two and three of 2024.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to successfully participate PT for the hematology analytes Hematocrit (HCT, Analyte #0785) and Hemoglobin (HGB, Analyte #0795) during events two and three of 2024, resulting in the initial unsuccessful PT performance. Findings Include: 1. Review of the CASPER Report 0155D, ran on 11-01-2024, identified the initial unsuccessful PT performance for the hematology analytes Hematocrit (HCT, Analyte #0785) and Hemoglobin (HGB, Analyte #0795). HEMATOLOGY HCT - EVENT-2, 2024 = 0% - Unsatisfactory HCT - EVENT-3, 2024 = 0% - Unsatisfactory HGB - EVENT-2, 2024 = 0% - Unsatisfactory HGB - EVENT-3, 2024 = 0% - Unsatisfactory 2. Review of API Core Chemistry PT event summaries confirmed the laboratory failed to participate, resulting in a score of 0% for HCT and HGB in PT events two and three of 2024.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to successfully participate PT for the specialty of hematology (Analyte #0760) during events two and three of 2024, resulting in the initial unsuccessful PT performance for the subspecialty. Findings Include: 1. Review of the CASPER Report 0155D, ran on 11-01-2024, identified the initial unsuccessful PT performance for the specialty of hematology. HEMATOLOGY Hematology - EVENT-2, 2024 = 33% - Unsatisfactory Hematology - EVENT-3, 2024 = 0% - Unsatisfactory 2. Review of API Core Chemistry PT event summaries confirmed the laboratory failed to participate in PT events two and three of 2024, resulting in the unsatisfactory scores for the specialty of hematology.
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 a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the specialties of chemistry and hematology resulting in the laboratory's initial unsuccessful PT performance for the specialty of hematology, subspecialty of routine chemistry and the following chemistry and hematology analytes: Chloride (Cl, Analyte #0355), Creatinine (Analyte # 0405), Glucose (Analyte #0415), Potassium (K, Analyte #0465), Sodium (Na, Analyte #0475), Blood Urea Nitrogen (BUN, Analyte #0505), Hematocrit (HCT, Analyte #0785) and Hemoglobin (HGB, Analyte #0795) (See D6016).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory director to ensure PT samples were tested as required. The laboratory failed participated in the API Core Chemistry PT events two and three of 2024 (See D2089 and D2123); the laboratory failed to successfully participate in PT for the subspeciality of routine chemistry (See D2097) and the routine chemistry analytes Chloride (Cl, Analyte #0355), Creatinine (Analyte # 0405), Glucose (Analyte #0415), Potassium (K, Analyte #0465), Sodium (Na, Analyte #0475), and Blood Urea Nitrogen (BUN, Analyte #0505) (See D2096) during PT events two and three of 2024; and the laboratory failed to successfully participate in PT for the specialty of hematology (See D2131) and the hematology analytes Hematocrit (HCT, Analyte #0785) and Hemoglobin (HGB, Analyte #0795) (See D2130) during PT events two and three of 2024.