

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D2153895	<b>(X3) Date Survey Completed</b> 11/04/2022
<b>Name of Provider or Supplier</b> Midwest Institute For Minimally Invasive Therapies	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CASPER Report 0155D and review of College of American Pathologists (CAP) analyte scorecard, and interview with a laboratory representative (IM) the laboratory failed to successfully participate in proficiency testing (PT) for the hematology analyte prothrombin time during events one, two, and three of 2022, resulting in the subsequent unsuccessful performance for prothrombin time. See D2130.</p>
<b>D2130</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p>

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 review of the CASPER Report 0155D and review of College of American Pathologists (CAP) analyte scorecard and interview with a laboratory representative (IM) found the laboratory failed to successfully participate in proficiency testing (PT) for the hematology analyte prothrombin time during events one, two, and three of 2022, resulting in the subsequent unsuccessful performance. Findings include: 1. Review of the CASPER Report 0155D revealed that the subsequent unsuccessful PT performance occurred during CAP PT events one, two, and three of 2022, as listed below. Hematology EVENT -1, 2022 - Prothrombin Time - 40% Unsatisfactory EVENT -2, 2022 - Prothrombin Time - 60% Unsatisfactory EVENT -3, 2022 - Prothrombin Time - 60% Unsatisfactory 2. Review of CAP PT analyte scorecard for prothrombin time PT in 2022 confirmed the subsequent unsuccessful PT performance for the analyte prothrombin time for events one, two, and three of 2022. 3. A phone interview on 11-4-2022, at 10:24 am, with a laboratory representative (IM) confirmed the subsequent unsuccessful PT performance for the analyte prothrombin time for events one, two, and three of 2022.

**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 review of the CASPER Report 0155D and review of College of American Pathologists (CAP) analyte scorecard the laboratory director failed to ensure laboratory personnel are performing prothrombin time testing as required to ensure accurate and reliable results in 2022 due to subsequent unsuccessful proficiency testing performance. See D6014.

**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 review of the CASPER Report 0155D and review of College of American Pathologists (CAP) analyte scorecard the laboratory director failed to ensure laboratory personnel are performing prothrombin time testing as required to ensure accurate and reliable results in 2022 due to unsuccessful proficiency testing

performance. Findings Include: 1. The laboratory has failed to successfully participate in proficiency testing for prothrombin time testing for three of three PT events in 2022 resulting in subsequent unsuccessful proficiency testing performance. See D2130.