

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 01D0305481	<b>(X3) Date Survey Completed</b> 05/10/2022
<b>Name of Provider or Supplier</b> Imc Diagnostic And Medical Clinic	<b>Street Address, City, State</b> 1700 Springhill Ave Suite 100, Mobile, AL	
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 a review of the CMS (Centers for Medicare and Medicaid) CASPER reports, and a telephone interview with testing personnel, the surveyor determined the laboratory failed to successfully participate in Valproic Acid proficiency testing for two consecutive testing events, Event #3, 2021 and Event #1, 2022. These two consecutive failures resulted in initial unsuccessful proficiency testing. The findings include: Refer to D2118.</p>
<b>D2118</b>	<p><b>TOXICOLOGY</b> CFR(s): 493.845(f)</p>

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 review of the CMS (Centers for Medicare and Medicaid) CASPER reports, and a telephone interview with testing personnel, the surveyor determined the laboratory failed to satisfactorily perform in Valproic Acid proficiency testing for two consecutive testing events, Event #3, 2021 and Event #1, 2022. These two consecutive failures resulted in initial unsuccessful proficiency testing. The findings include: 1. A review of the CASPER reports revealed the laboratory scored the following: a) Valproic Acid, Event #3, 2021 60 % b) Valproic Acid, Event #1, 2022 60 % These two consecutive failures resulted in initial unsuccessful proficiency testing. 2. During a telephone interview on May 10, 12:58 PM, the testing personnel stated she was aware of the failures. She further explained she believe the failures resulted from mixing errors (bubbles in the specimens).