

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0305481	<b>(X3) Date Survey Completed</b>  08/31/2022
<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>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the validation documentation for the current lot number of Innovin Prothrombin Time (PT) reagent on the Sysmex CA-620 analyzer, a review of the product insert, and an interview with the General Supervisor, the surveyor determined the laboratory failed to ensure all information was entered in the instrument when the new lot number (#) of Innovin was implemented, and failed to ensure validation procedures included manual checks of the INR (International Normalized Ratio) calculation on the instrument. This was noted on one of one lot numbers of PT reagent in use. The findings include: 1. During the entrance tour on 8/30/2022 at approximately 11:30 AM, the General Supervisor stated coagulation testing (PT [Prothrombin Time] and PTT [Partial Thromboplastin Time]) was performed on the new Sysmex CA-620. The surveyor requested a review of the current lot # and ISI (International Sensitivity Index) of Innovin reagent on the instrument. The Supervisor provided an instrument printout with the following: PT 06/23/2022 [The date the new lot # was entered] PT INN 549797 [The Lot # of Innovin in use] 05/11/2024 [The Innovin expiration date] NORMAL 10.00 sec [The Normal Patient Mean] ISI 1.04 2. On 8/31/2022 at 9:40 AM, the surveyor requested the package insert and the validation records for the current lot # of Innovin reagent. The General Supervisor provided the Innovin package insert and data from 25 normal patients used for the calculation of the Normal Patient Geometric Mean (NPGM) which equaled 10.03552, rounded to 10.0 seconds. However, the surveyor noted the package insert and the NPGM calculation were for Innovin Lot #564610, Expiration</p>

Date-01/20/2025 with an ISI of 1.04, not Lot #549797, Expiration Date-05/11/2024 as viewed on the instrument printout during the entrance tour. 3. During an interview on 8/31/2024 at 9:45 AM, the surveyor reviewed the above information with the General Supervisor, and asked about the discrepancy. The Supervisor investigated and stated on 6/23/2022 she had carefully updated the Sysmex CA-620 with the new NPGM (10.0) and ISI (1.04) for Innovin Lot #564610, however she had forgotten to update with the new Lot #/Expiration, so the previous reagent Lot #/Expiration remained in the system. 4. As the interview continued at 9:55 AM, the surveyor asked if the laboratory manually checked the INR (International Normalized Ratio) calculation on the instrument when implementing a new lot number of Innovin. The General Supervisor confirmed she had not because she did not know it was required.  
SURVEYOR ID #32558 Licensure and Certification Surveyor