

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0992365	(X3) Date Survey Completed 07/14/2021
Name of Provider or Supplier Metabolism Endocrinology And Diabetes (Mend)	Street Address, City, State 24 Frank Lloyd Wright Drive, Ann Arbor, MI	
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
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) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to verify performance specifications for the Abbott iStat Chem 8 CG4+ cartridges prior to testing patients for 9 (October 2020 to July 2021) of 9 months the test system has been used. Findings include: 1. The surveyor requested the verification of performance specification data for the Abbott iStat Chem 8 CG4+ test system and it was not made available. 2. A review of patient test records revealed a total of 21 patient tests were performed between 10/1/20 and 7/14/21. 3. An interview on 7/14/21 at 10:38 am with TC1 revealed the laboratory started patient testing using the Abbott iStat Chem 8 CG4+ test system on 10/1/20 and did not perform verification of performance specification procedures prior to testing patients.</p>