

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0897499	(X3) Date Survey Completed 09/30/2021
Name of Provider or Supplier Idicula Medical Associates Md Pa	Street Address, City, State 10065 Cortez Blvd, Brooksville, FL	
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
D0000	An announced CLIA initial survey was conducted at Idicula Medical Associates MD PA on 09/30/21. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level 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 Testing Personnel #B, the performance verification failed to verify the calculations for the anion gap and the estimated glomerular filtration rate (eGFR) during the laboratory information system (LIS) installation. The laboratory started patient testing May 10th, 2021. Findings included: Record review of the LIS performance verification records (installation date 04/28/21) revealed verification of the calculation for the anion gap and the estimated eGFR was not included. Record review of the "Validation of the Laboratory Information System" procedure revealed a section titled "Validation of Calculations:" which stated "1. Validate all LIS calculated results initially, annually and after any system change that impacts calculation for each protocol analyte and method." Interview on 09/30/21 at 01:05 PM, Testing Personnel #B confirmed that the LIS performance verification did not include verifying the anion gap and eGFR calculations.</p>