

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0663215	(X3) Date Survey Completed 05/21/2021
Name of Provider or Supplier Laboratorio Clinico Laracuate	Street Address, City, State Calle Mendez Vigo #291, Dorado, PR	
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 review of validation records of the Beckman Coulter DxH520 system for the complete blood cells (CBC) tests and laboratory director interview on May 21, 2021 at 10:20 AM, it was determined that the laboratory failed to verify that the manufacturer's CBC reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 1,420 out of 1,420 CBC patient results from January 4, 2021 to May 20, 2021. The findings include: 1. On May 21, 2021 at 10:20 AM, the Beckman Coulter DxH520 system records showed that the laboratory laboratory performed the validation procedures on December 16, 2020 and it did not verify that the manufacturer's CBC reference intervals (normal values) are appropriate for the laboratory's patient population. 2. The laboratory director confirmed on May 21, 2021 at 10:20 AM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting CBC patient results. 3. The laboratory processed and reported 1,420 out of 1,420 CBC patient results from January 4, 2021 to May 20, 2021.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p>

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of validation records of the Beckman Coulter DxH520 system for the complete blood cells (CBC) tests and laboratory director interview on May 21, 2021 at 10:20 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for CBC tests from January 4, 2021 to May 20, 2021. Refer to D5421 (The laboratory did not verify that the manufacturer's CBC reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 1,420 out of 1,420 CBC patient results from January 4, 2021 to May 20, 2021.