

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658291	(X3) Date Survey Completed 07/23/2019
Name of Provider or Supplier Lab Clin Borinquen - Las Lomas	Street Address, City, State Carr 21 U-3 Urb Las Lomas, Rio Piedras, 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 new hematology system (Coulter DXH 600) for complete cell count (CBC) tests and general supervisor interview on July 23, 2019 at 1:45 PM, 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 15,728 CBC tests during the year 2018. The findings include: 1. On July 23, 2019 at 1:45 PM, the validation records of the Coulter DXH 600 system showed that the laboratory laboratory performed the validation procedures for this new system on January 29, 2018. However, the validation records showed that the laboratory did not verify that the manufacturer's CBC reference intervals (normal values) are appropriate for the laboratory's patient population. 2. The general supervisor confirmed that the the validation records of the Coulter DXH 600 system did not include the verification of the manufacturer's CBC reference intervals. She stated that this performance characteristic was verified but the records were not available. 3. The laboratory processed and reported 15,728 CBC tests during the year 2018.</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 new hematology system (Coulter DXH 600) for complete cell count (CBC) tests and general supervisor interview on July 23, 2019 at 1:45 PM, it was determined that the laboratory director failed to comply with the requirements for CBC tests. Refer to D 5421 (The laboratory failed to verify that the manufacturer's CBC reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 15,728 CBC tests during the year 2018).

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:
Based on review of validation records of the new hematology system (Coulter DXH 600) for complete cell count (CBC) tests and general supervisor interview on July 23, 2019 at 1:45 PM, it was determined that the technical supervisor failed to follow quality control procedures (verifying the performance specifications of new instrument) before reporting 15,728 CBC tests during the year 2018. Refer to D 5421.