

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0680117	(X3) Date Survey Completed 12/13/2019
Name of Provider or Supplier Laboratorio Clinico Quebrada	Street Address, City, State Road 455 Km 2 Hm 2 Bo Quebrada, Camuy, 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 special chemistry performance specifications records review (november 2018) and laboratory general supervisor interview on December 13, 2019, 2016 at 11:30 A.M., it was determined that the laboratory failed to complete the evaluation of the performance specifications of the new special tests system. The findings include: 1. The laboratory acquired on November 2018 a new system to perform special chemistry tests (Access 2). 2. The performance specifications records showed that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. 3. The laboratory general supervisor confirmed on December 13, 2019 at 11:30 A.M. , that the laboratory did not verify if the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population prior to begin to test patient's samples. 4. The laboratory processed and reported approximately 7,266 special chemistry tests performed by Access 2 system since November 2018.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established</p>

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 special chemistry performance specifications records review (November 2018) and laboratory general supervisor interview on December 13, 2019, 2016 at 11:30 A.M., it was determined that the laboratory director did not assure that the evaluation of the performance specifications of the new special tests system (Access 2) was completed. The finding includes: 1. The laboratory failed to complete the evaluation of the performance specifications of the new special tests system. Refer to D5421.