

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0995540	(X3) Date Survey Completed 09/11/2018
Name of Provider or Supplier Laboratorio Clinico Borinquen-Juncos	Street Address, City, State Juncos Plaza Iii Local D3, Juncos, 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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on comparison test results records review in years 2017-2018, 2017 laboratory annual volume records review and laboratory general supervisor interview on September 11, 2018 at 10:00 AM, it was determined that the laboratory failed to evaluates twice a year the relationship of the WBC differential results between the manual method and the Sysmex 1000i hematology system. The findings include: 1. The laboratory performed automatic cell differential by Sysmex 1000i hematology system. 2. The laboratory established to evaluate twice a year the relationship between the WBC manual and automatic cell differential. 2. Review the test result comparison records in years 2017-2018, showed that the laboratory did not evaluate twice a year the relationship of the WBC differential results between the manual method and the Sysmex XS1000i system since 2017. But the laboratory performed the test result comparison on 2016. 3. From January 2017 to December 31, 2017, the 2017 annual volume records showed that the laboratory collected and processed two thousand six hundred three (2,603) Complete Blood Count by the Sysmex XS1000i hematology system. 4. The laboratory general supervisor confirmed on September 11, 2018 at 10:00 AM, that the laboratory failed to evaluate twice a year a relationship between the manual cell differential and automatic cell differential by Sysmex 1000i hematology system since July 2017.</p>
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

	<p>CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review in years 2017-2018 and laboratory general supervisor interview on September 11, 2018 at 10:00 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for post analytic systems. The findings include: 1. The laboratory established on Quality assessment program manual to evaluate twice a year the relationship between WBC manual and automatic differential. 2.The laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential. Refer to D5775.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review in years 2017-2018 and laboratory general supervisor interview at 10:00 AM on September 11, 2018, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. The finding includes: 1. The quality assessment records in years 2017-2018, showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for post analytical system. Refer to D5791.</p>
<p>D6144</p>	<p>GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463</p> <p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment records review in years 2017-2018 and laboratory general supervisor interview on September 11, 2018 at 10:00 AM, it was determined that the general supervisor failed to monitor and evaluate the requirements for postanalytical systems. The finding includes: 1. The laboratory failed to evaluate twice a year the relationship of the WBC differential results between the manual method and the Sysmex 1000i hematology system. Refer to D5775.</p>
<p>D6177</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3)</p>

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on quality assessment records review in years 2017-2018 and laboratory general supervisor interview on September 11, 2018 at 10:00 AM, it was determined that the testing personnel failed to monitor and evaluate the requirements for postanalytical systems. The finding includes: 1. The laboratory failed to evaluate twice a year the relationship of the WBC differential results between the manual method and the Sysmex 1000i hematology system. Refer to D5775.