

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D2129969	<b>(X3) Date Survey Completed</b>  10/19/2018
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Villa Ana Aguas Buenas Ii	<b>Street Address, City, State</b>  Calle Dr Rafael Lasa # 48, Aguas Buenas, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<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 Cell Dyn Emerald system for complete cell count (CBC) test, validation records of Architect C4000 system for routine chemistry tests, annual test volume record and laboratory director interview on October 19, 2018 at 10:10 AM, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) of those systems, are appropriate for the laboratory's patient population before reporting CBC and routine chemistry patients tests from June 23, 2018 to October 18, 2018. The findings include:</p> <ol style="list-style-type: none"> <li>1. On October 19, 2018 at 10:10 AM, the Cell Dyn Emerald system validation records showed that the laboratory performed the validation procedures on April 12, 2018 and it did not verify that the manufacturer's CBC reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patients tests.</li> <li>2. On October 19, 2018 at 8:40 AM, the Architect C4000 system validation records showed that the laboratory performed the validation procedures on June 22, 2018 and it did not verify that the manufacturer's routine chemistry tests reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patients tests.</li> <li>3. The laboratory director confirmed on October 19, 2018 at 10:10 AM, that those validations did not include the manufacturer's reference intervals verification.</li> <li>4. The annual test volume record showed that the laboratory processed</li> </ol>

620 CBC tests in the hematology specialty and 4,683 routine chemistry tests from June 23, 2018 to October 18, 2018.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of validation records of the Cell Dyn Emerald system for complete cell count (CBC) test, validation records of Architect C4000 system for routine chemistry tests, annual test volume record and laboratory director interview on October 19, 2018 at 10:10 AM, it was determined that the laboratory director failed to comply with the analytic system requirements for the CBC and routine chemistry tests from June 23, 2018 to October 18, 2018. The finding includes: 1. Refer to D 5421 ( The laboratory failed to verify that the manufacturer's reference intervals (normal values) of the Cell Dyn Emerald and Architect C4000 systems are appropriate for the laboratory's patient population before reporting CBC and routine chemistry patients tests from June 23, 2018 to October 18, 2018).