

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0901302	(X3) Date Survey Completed 10/06/2020
Name of Provider or Supplier Laboratorio Clinico Vivianette	Street Address, City, State Carr 459 Km 01 Bo Corrales, Aguadilla, 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
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on hematology quality control records (2019-2020) and interview with the laboratory supervisor on October 6, 2020 at 11:00 A.M.,it was determined that the laboratory failed to ensure compliance with the analytic system requirements for hematology. The findings include: 1. The laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). Refer to D5401.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of hematology records (2019-2020) and laboratory general supervisor interview on October 6, 2020 at 11:000 a.m. , it was determined that the laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). The findings include: 1. . The laboratory perform PT (Prothrombin time) and PTT (Partial thromboplastin time) tests by Coatron M2</p>

	<p>system. 2. The laboratory had in routine use on October 6, 2020 the following thromboplastin reagent: Lot. # 853668, exp. 9/30/2022. 3. Hematology records were reviewed since January 2020. The records showed that the laboratory did not document nor establish a normal population prothrombin (PT) mean for the thromboplastin new lot number began to use on January 22, 2020. 4. The laboratory processed and reported seventy one (71) patient's samples since January 22, 2020 with the incorrect INR. The laboratory uses the former laboratory PT mean of 11.9 secs. 5. The laboratory general supervisor confirmed on October 6, 2020 at 11:30 A.M. , that the laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio).</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on hematology quality control records review (2019-2020) and interview with the laboratory general supervisor on October 6, 2020 at 11:00 A.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements for hematology. The finding includes: 1. The laboratory director failed to ensure compliance with the hematology requirements. Refer to D6093.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on hematology quality control records (2019-2020) and interview with the laboratory supervisor on October 6, 2020 at 11:00 A.M.,it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for hematology. The findings include: 1. The laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). Refer to D5401.</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 hematology quality control records review (2019-2020) and laboratory general supervisor interview on October 6, 2020 at 11:00 AM, it was determined that</p>

the general supervisor failed to follow quality control procedures for hematology. The finding includes: 1. The laboratory failed to follow the manufacturer's instructions for calculating INR (International Normalized Ratio). Refer to D5401.