

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658002	(X3) Date Survey Completed 05/10/2019
Name of Provider or Supplier Quest Diagnostics Laboratorio De Analisis Clinico	Street Address, City, State Carr 2 Km 57 Hm2 Cruce Davila, Barceloneta, 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 review (2018-2019) and interview with the laboratory director on May 10, 2019 at 11:30 A.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for hematology. Refer D5405 (the laboratory failed to follow manufacturer's instructions when patient specimens were tested for Complete Blood Count by the Coulter Act 5 diff hematology system).</p>
D5405	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on manufacturer's instructions, hematology quality control records review (years 2018-2019) and laboratory director interview at 11:30 a.m. on May 10, 2019, it was determined that the laboratory failed to follow manufacturer's instructions when patient specimens were tested for (CBC) Complete Blood Count by the Coulter Act 5 diff hematology system. The findings include: 1. The laboratory uses Coulter Act 5</p>

	<p>diff to perform hematology patient tests. 2. The manufacturer establishes that three levels of control material (low, normal and high) must be included each day of testing. 3. Review of hematology quality control records from January 2018 to April 2019, showed that the laboratory did not include the three levels of controls during the following days: February 1, 2018 to February 6, 2018. 4. The laboratory processed and reported thirty-eight (38) Complete Blood Count patient's samples those days. 5. The laboratory director confirmed that the laboratory failed to follow manufacturer's instructions when patient specimens were tested for (CBC) Complete Blood Count by the Coulter Act 5 diff hematology system.</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 (2018-2019) and interview with the laboratory director on May 10, 2019 at 11:30 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 (2018-2019) and laboratory director interview on May 10, 2019 at 11:45 A.M, it was determined that the laboratory director failed to ensure compliance with the hematology requirements for analytic systems. The findings include: 1. The laboratory failed to follow manufacturer's instructions when patient specimens were tested for (CBC) Complete Blood Count by the Coulter Act 5 diff hematology system. Refer to D5405.</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 (2018-2019) and laboratory general supervisor interview on May 10, 2019 at 11:50 AM, it was determined that the general supervisor failed to follow quality control procedures. The finding includes: 1.</p>

The laboratory general supervisor did not evaluate aspects regarding: hematology control procedures. Refer to D5405.