

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0684520	(X3) Date Survey Completed 10/16/2018
Name of Provider or Supplier Laboratorio Clinico Caribe	Street Address, City, State Edificio Medical Ophthalmic Plaza, Bayamon, 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 Coulter Act 5 diff control plus manufacturer's instructions, hematology quality control records (years 2017, 2018) review and laboratory director interview on October 16, 2018 at 9:20 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for the CBC tests. Refer to D 5504. The laboratory failed to used the complete blood count (CBC) controls materials that have exceeded their expiration date and failed to include the three levels of control materials each day of testing.</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 Coulter Act 5 diff control plus manufacturer's instructions, hematology quality control records (years 2017, 2018) review and laboratory director interview on October 16, 2018 at 9:20 AM, it was determined that the laboratory failed to used the complete blood count (CBC) controls materials that have exceeded their expiration</p>

date and failed to include the three levels of control materials each day of CBC testing. The findings include: 1. The laboratory analyzed and reported CBC tests by the Coulter Act 5 diff system. 2. The laboratory used the Coulter Act 5 diff control plus materials for the quality control of the CBC tests. 3. The Coulter Act 5 diff control plus manufacturer instructed the laboratory to use the control materials until the expiration date or with 15 consecutive days open-vial stability and to include the three levels of control materials each day of testing.. 4. On October 16, 2018 at 9:20 AM, the hematology quality control records showed that the laboratory used the following lots of CBC control materials that have exceeded their expiration date: a. Normal level control (Lot 370318 exp. on May 5, 2018): used on May 18, 2018; May 17, 2018, May 16, 2018 and May 11, 2018. b. Low level control (lot 360318 Exp. May 5, 2018): used on May 18, 2018; May 17, 2018, May 16, 2018, May 14, 2018 and May 11, 2018. c. The laboratory did not include the High level control material on May 18, 2018; May 17, 2018, May 16, 2018 and May 11, 2018. 5. The laboratory director confirmed on October 16, 2018 at 9:20 AM, that the hematology records showed that the laboratory used control materials that have exceeded their expiration date and during the following days the high control material was not included: May 18, 17, 16 and 11, 2018. She stated that the laboratory had problem with the control shipment. 6. The laboratory analyzed and reported CBC patients specimens the following dates: Dates Patients specimens May 18, 2018 7 May 17, 2018 9 May 16, 2018 9 May 14, 2018 5 May 11, 2018 6

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:
Based on Coulter Act 5 diff control plus manufacturer's instructions, hematology quality control records (years 2017, 2018) review Pointe 180 instrument manufacturer's instructions, Pointe 180 linearity records (March 2016) review and laboratory director interview on October 16, 2018 at 11:00 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system. The finding includes: 1. The laboratory director did not comply with the analytical systems requirements for the CBC tests. Refer to D 6093. 2. The laboratory director did not comply with the analytical systems requirements for the Pointe 180 linearity check . Refer to D 6095.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:
Based on Coulter Act 5 diff control plus manufacturer's instructions, hematology

quality control records (years 2017, 2018) review and laboratory director interview on October 16, 2018 at 9:20 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for the CBC tests. Refer to D 5024.

D6095

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:

Based on Pointe 180 instrument manufacturer's instructions, Pointe 180 linearity records (March 2016) review and laboratory director interview on October 16, 2018 at 11:00 AM, it was determined that the laboratory failed to follow manufacturer's instructions to perform a periodic verification of the instrument linearity from January 1, 2017 to October 15, 2018. The findings include: 1. The laboratory performed and reported the patients glucose tests by the Pointe 180 instrument from January 1, 2017 to October 15, 2018. 2. The Pointe 180 manufacturer instructed the laboratory that is advisable to perform a periodic verification of the instrument linearity. 3. On October 16, 2018 at 11:00 AM, the Pointe 180 linearity records showed that the laboratory checked the instrument linearity on March 30, 2016. 4. The laboratory performed and reported 289 out of 289 patients glucose test by the Pointe 180 instrument from January 1, 2017 to October 15, 2018.