

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0663215	<b>(X3) Date Survey Completed</b> 03/06/2019
<b>Name of Provider or Supplier</b> Laboratorio Clinico Laracuate	<b>Street Address, City, State</b> Calle Mendez Vigo #291, Dorado, 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>D5024</b>	<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 manufacturer's instructions, Complete Blood Count (CBC) quality control (QC) records ( years 2017, 2018 and 2019) review and interview with the general supervisor on March 6, 2019 at 9:45 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for CBC tests. The finding includes: 1. Refer to D 5405. (The laboratory failed to follow manufacturer's instructions for the CBC QC procedures when 1,332 out of 1,332 patient specimens were tested for CBC by the Coulter Act 5 diff hematology system from January 6, 2018 to April 30, 2018).</p>
<b>D5405</b>	<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, Complete Blood Count (CBC) quality control records ( years 2017, 2018 and 2019) review and interview with the general supervisor on March 6, 2019 at 9:45 AM, it was determined that the laboratory failed</p>

to follow manufacturer's instructions for the CBC quality control (QC) procedures when 1,332 out of 1,332 patient specimens were tested for CBC by the Coulter Act 5 diff hematology system from January 6, 2018 to April 30, 2018. The findings include:

1. The laboratory uses Coulter Act 5 diff system to perform the CBC tests.
2. The manufacturer establishes that three levels of control material (low, normal and high) must be included each day of testing.
3. On March 6, 2019 at 9:45 AM, review of CBC quality control records ( years 2017, 2018 and 2019) showed that the laboratory did not have available the QC data nor the Levey Jennings (LJ) charts of the three levels CBC control values for the following periods: from January 6, 2018 to January 31, 2018, from March 1, 2018 to March 23, 2018 and from April 8, 2018 to April 30, 2018.
4. The general supervisor confirmed on March 6, 2019 at 9:45 a.m., that the laboratory did not have available those CBC data nor the CBC control values LJ charts due to the Act 5 diff's information system was damage and those data were lost.
5. The laboratory processed and reported the following patients specimens from January 6, 2018 to April 30, 2018:
  - a. From January 6, 2018 to January 31, 2018: 450 out of 450 CBC's patients specimens.
  - b. From March 1, 2018 to March 23, 2018: 404 out of 404 CBC's patients specimens.
  - c. From April 8, 2018 to April 30, 2018: 438 out of 438 CBC's patients specimens

**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 manufacturer's instructions, Complete Blood Count (CBC) quality control (QC) records ( years 2017, 2018 and 2019), personnel records files and interview with the with the general supervisor on March 6, 2019 at 12:08 PM, 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. Refer to D 6093. 2. The laboratory director did not ensure the competency of the laboratory general supervisor. Refer to D 6103. 3. The laboratory director did not specify in writing the duties and responsibilities of the laboratory general supervisor. Refer to D 6107.

**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 manufacturer's instructions, Complete Blood Count (CBC) quality control (QC) records ( years 2017, 2018 and 2019) review and interview with the general supervisor on March 6, 2019 at 9:45 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for CBC tests. Refer to D 5024.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of personnel records files and interview with the with the general supervisor on March 6, 2019 at 12:08 PM, it was determined that the laboratory director did not ensure the competency of the laboratory general supervisor from January 9, 2017 to January 10, 2019. The findings include: 1. On March 6, 2019 at 9:45 AM, the general supervisor personnel files did not include her competence evaluation from January 9, 2017 to January 10, 2019. 2. The laboratory director did not establish a written protocol to evaluate the competency of the laboratory general supervisor.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of personnel records files and interview with the with the general supervisor on March 6, 2019 at 12:08 PM, it was determined that the laboratory director did not specify in writing the duties and responsibilities of the laboratory general supervisor from January 9, 2017 to January 10, 2019. The finding includes: 1. On March 6, 2019 at 9:45 AM, the general supervisor personnel files did not include written duties nor responsibilities from January 9, 2017 to January 10, 2019.