

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0715748	<b>(X3) Date Survey Completed</b>  02/28/2018
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Borges	<b>Street Address, City, State</b>  Calle Arzuaga Num 168, Rio Piedras, 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>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on Coulter Act 5 diff system calibration records (2016) reviewed, lack of Coulter Act 5 diff system calibration records (2017) and technical supervisor interview on February 28, 2018 at 10:10, it was determined that the laboratory failed to perform the calibration procedures with at least the frequency recommended by the manufacturer's (each six months) for the Coulter Act 5 diff system when 3,300 out of 3,300 CBC patients specimens were processed and reported from January 2017 to September 15, 2017. The findings include: 1. The laboratory uses the Coulter Act 5 diff system to analyzer and report the CBC patient's specimens. 2. The manufacturer's instructions establishes that the laboratory perform the calibration procedures each six months. 3. There Coulter Act 5 diff system calibration records (2017) were not available in the laboratory. 4. The general supervisor stated on February 28, 2018 at 10:15, that the laboratory performed the Coulter Act system calibration every six months but she can not found the Coulter Act 5 diff system calibration records (2017). 5. The laboratory processed and reported 3,300 out of 3,300 CBC patients specimens by the Coulter Act 5 diff system from January 2017 to September 15, 2017.</p>

**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 system calibration records (2016) reviewed, lack of Coulter Act 5 diff system calibration records (2017) and technical supervisor interview on February 28, 2018 at 10:10, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the CBC tests processed and reported by the Coulter Act 5 diff system when 3,300 out of 3,300 CBC patients specimens were processed and reported from January 2017 to September 15, 2017. The finding includes: 1. The laboratory director failed to ensure compliance with the analytic system requirements of the CBC tests. Refer to D 5437. (The laboratory did not to perform the calibration procedures with at least the frequency recommended by the manufacturer's (each six months) for the Coulter Act 5 diff system when 3,300 out of 3,300 CBC patients specimens were processed and reported from January 2017 to September 15, 2017).

**D6117**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:

Based on Coulter Act 5 diff system calibration records (2016) reviewed, lack of Coulter Act 5 diff system calibration records (2017) and technical supervisor interview on February 28, 2018 at 10:10, it was determined that technical supervisor failed to ensure compliance with the requirements for the analytic systems of the CBC tests. Refer to D 5437. (The laboratory did not to perform the calibration procedures with at least the frequency recommended by the manufacturer's (each six months) for the Coulter Act 5 diff system when 3,300 out of 3,300 CBC patients specimens were processed and reported from January 2017 to September 15, 2017).