

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0658031	<b>(X3) Date Survey Completed</b>  02/23/2021
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Boqueron, Inc	<b>Street Address, City, State</b>  Munoz Rivera #63, Boqueron, 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>D5469</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on hematology quality control records review (years 2020 - 2021) and laboratory director interview on February 23, 2021 at 10:10 AM, it was determined that the laboratory failed to verify the stated value of the new lot CBC commercially assayed control materials from June 20, 2020 to August 14, 2020. The findings include : 1. The laboratory uses Mindray BC5390 to perform CBC (complete blood count) patient's samples tests. 2. Review of records from January 2020 to January 2021, the hematology quality control records showed that the laboratory did not verify the new lots of CBC control materials (lot BCN 2007BL, BCN2007BN, BCN2007BH) ) prior to placed in routine on June 20, 2020 (those lots of CBC control materials were used in the laboratory until August 14, 2020). 3. The laboratory director confirmed on February 23, 2021 at 10:10 AM, that the laboratory did not verify those new lots of CBC control materials prior to placed in routine. 4. The laboratory diretor stated on February 23, 2021 at 10:10 AM, that the laboratory</p>

processed and reported one hundred eight (108) CBC patient's samples from June 20, 2020 to August 14, 2020.

**D5473**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on hematology procedures manual, hematology quality control records review and laboratory director interview on February 23, 2021 at 10:20 AM, it was determined that the laboratory failed to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics. The findings include: 1. The laboratory establish in the procedures manual, that the laboratory check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics. 2. Review of hematology quality control records from January 2020 to January 2021, the records showed that the laboratory did not check nor document the reactivity of Wright's stain reagent, each day of use, in the following days: Date #Hema Differential cells 1/10/2020 1 6/1 /2020 1 2/20/2021 1 2/22/2021 1 3. The laboratory director confirmed on February 23, 2021 at 10:20 AM, that the laboratory did not check nor document the reactivity of Wright's stain reagent from January 2020 to January 2021. 4. The laboratory processed and reported four (4) WBC differential manual those days.

**D5783**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

A. Based on hematology quality control statistical parameters from July 2020 and laboratory director interview on February 23, 2021 at 10:30 AM, it was found that the laboratory did not evaluate nor define the statistical values during July 2020 of the commercial control material used by the Mindray BC5390 hematology instrument. The findings include: 1. The laboratory did not have any statistical data (Levy-Jennings, control value mean and limits) of the control materials used in July 2020. 2. The laboratory director stated that for July 2020 the laboratory performed fifty one (51) CBC patient's samples. B. Based on hematology quality control statistical parameters from September 2020 to November 2020 and laboratory director interview on February 23, 2021 at 10:30 AM, it was found that the laboratory did not evaluate nor define the statistical values during July 2020 of the commercial control material

used by the Start 4 hematology instrument (PT-PTT)(Prothrombine Time and Partial Thrombine Time). The findings include: 1. The laboratory did not have any statistical data (Levy-Jennings, control value mean and limits) of the control materials used from September 2020 to November 2020. 2. The laboratory director stated that from September to November 2020 the laboratory performed thirty nine (39) PT - PTT patient's samples. C. Based on hematology quality control statistical parameters from November 2020 to December 2020 and laboratory director interview on February 23, 2021 at 10:30 AM, it was found that the laboratory did not evaluate nor define the statistical values during July 2020 of the commercial control material used by the Mini Cube hematology instrument (Sedimentation rate). The findings include: 1. The laboratory did not have any statistical data (Levy-Jennings, control value mean and limits) of the control materials used from November 2020 to December 2020. 2. The laboratory director stated that from November 2020 to December the laboratory performed sixty three (63) Sed Rate patient's samples. D. Based on routine chemistry quality control statistical parameters from October 2020 to December 2020 and laboratory director interview on February 23, 2021 at 10:30 AM, it was found that the laboratory did not evaluate nor define the statistical values during those months of the commercial control material used by the Cobas c311 routine chemistry instrument. The findings include: 1. The laboratory did not have any statistical data (Levy-Jennings, control value mean and limits) of the control materials used from October 2020 to December 2020. 2. The laboratory director stated that for July 2020 the laboratory performed two hundred ninety eight (298) routine chemistry patient's samples. E. Based on special chemistry quality control statistical parameters from July 2020 to December 2020 and laboratory director interview on February 23, 2021 at 10:30 AM, it was found that the laboratory did not evaluate nor define the statistical values during those months of the commercial control material used by the Cobas c411 especial chemistry instrument. The findings include: 1. The laboratory did not have any statistical data (Levy-Jennings, control value mean and limits) of the control materials used from July 2020 to December 2020. 2. The laboratory director stated that for July 2020 the laboratory performed two hundred seventy three (273) special chemistry patient's samples.

**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 hematology, routine chemistry and special chemistry quality control records review (years 2020-2021) and laboratory director interview at 11:30 AM on February 23, 2021, it was found that the laboratory director did not assure that quality control procedures related to evaluation hematology stain, evaluation of statistical control parameters and evaluation of new reagents lots were followed. The findings include: 1. The laboratory failed to verify the stated value of the new lot CBC (Complete blood count) commercially assayed control materials from June 20, 2020 to August 14, 2020. Refer to D5469. 2. The laboratory failed to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics. Refer to D5473. 3. The laboratory did not evaluate nor define the

statistical values during July 2020 of the commercial control material used by the Mindray BC5390, Start 4, Mini Cube hematology instrument and Cobas c311, c411 routine and special chemistry. Refer to D5783.

**D6144**

**GENERAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:

Based on hematology, routine chemistry and special chemistry quality control records review (years 2020-2021) and laboratory director interview at 11:30 AM on February 23, 2021, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. The findings include: 1. The laboratory failed to verify the stated value of the new lot CBC (Complete blood count) commercially assayed control materials from June 20, 2020 to August 14, 2020. Refer to D5469. 2. The laboratory failed to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics. Refer to D5473. 3. The laboratory did not evaluate nor define the statistical values during July 2020 of the commercial control material used by the Mindray BC5390, Start 4, Mini Cube hematology instrument and Cobas c311, c411 routine and special chemistry. Refer to D5783.