

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0707929	(X3) Date Survey Completed 02/05/2020
Name of Provider or Supplier Laboratorio Clinico Luis Munoz Rivera	Street Address, City, State Calle Munoz Rivera #21, Vega Alta, 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
D5469	<p>CONTROL PROCEDURES 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 review of coagulation quality control records review from years 2018-2020, review of patient data log from year 2018-2020 and interview with the laboratory director , it was found that the laboratory did not evaluate in Levy Jennings the values of the PT (prothrombin time) and PTT (partial thromplastin time) tests control material used by the BFT -II instrument. The findings include: 1. The laboratory establish to evaluate quality control data by Levy Jennings graphs(statical data , control value mean and limits). 2. The laboratory failed to evaluate the control value since December 4, 2019 to January 31, 2020. 3. The laboratory director confirmed on February 5, 2020 at 10:50 A.M., that the laboratory failed to evaluate in Levy Jennings since December 4, 2019. 4. The patient data log showed that the laboratory performed eleven coagulation (PT & PTT) patient samples since December 4, 2019 to January 31, 2020.</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 coagulation quality control records review (year 2018-2020) and interview with the laboratory supervisor on February 5, 2020 at 10:50A.M., it was determined that the laboratory director did not assure that the laboratory evaluate in Levy Jennings the values of the PT (prothrombin time) and PTT (partial thromplastin time) tests control material used by the BFT -II instrument. Refer to D5469.