

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0658247	<b>(X3) Date Survey Completed</b>  07/12/2019
<b>Name of Provider or Supplier</b>  Lab Clinico Metabolico	<b>Street Address, City, State</b>  1507 Calle Profesor Augusto Rodriguez, Santurce, 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 Coulter Act Diff 2 system manufacturer's instructions, preventive maintenance record, CBC's quality control records, laboratory annual volume records review and interview with the laboratory director on July 12, 2019 at 11:20 AM, it was determined that the laboratory failed to meet the analytic system requirements for Hematology specialty. Refer to D 5429 (The laboratory failed to follow written instructions for the daily preventive maintenance of the Coulter Act Diff 2 system when it processed 12, 397 complete cell count (CBC) tests during the year 2018 and processed 368 patient's specimens for CBC from January 14, 2019 to July 11, 2019). Refer to D 5469 (The laboratory failed to verify the stated value of the new lot CBC commercially assayed control materials from April 3, 2018 to November 16, 2018). Refer to D 5481 ( The laboratory failed to ensure that the CBC control materials values meet the laboratory's criteria for acceptability before reporting 75 out of 75 patient's specimens for CBC test results during the April, 2019 month).</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if</p>

applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on lack of room humidity chart records for the bacteriology area, laboratory annual volume records review and interview and laboratory director interview on July 12, 2019 at 9:40 AM, it was determined that the laboratory failed to monitor and document the room relative humidity of the bacteriology area since January 2018. The findings include: 1. On July 12, 2019 at 9:40 AM, the laboratory did not monitor nor document daily the room relative humidity of the bacteriology area since January 2018. 2. The laboratory director confirmed on July 12, 2019 at 9:40 , that the laboratory failed to monitor and document the relative humidity of the bacteriology area since January 2018. 3. The laboratory processed the patient's specimens for urine and throat culture. The laboratory annual volume records showed that the laboratory processed 174 patients cultures during year 2018.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on Coulter Act Diff 2 system manufacturer's instructions, preventive maintenance record, laboratory annual volume records review and interview with the laboratory director on July 12, 2019 at 10:30 AM, it was determined that the laboratory failed to follow written instructions for the daily preventive maintenance of the Coulter Act Diff 2 system when it processed 12, 397 complete cell count (CBC) tests during the year 2018 and processed 368 patient's specimens for CBC from January 14, 2019 to July 11, 2019. The findings include: 1. The laboratory processed the CBC patients's specimens by the Coulter Act Diff 2 system. 2. The manufacturer requires daily preventive maintenance of the Coulter Act Diff 2 system: startup, cleaning and shutdown. 3. On July 12, 2019 at 10:30 AM, preventive maintenance records of the Coulter Act Diff 2 system showed that the laboratory did not performed the daily maintenance since January 2018. 4. The laboratory director stated on July 12, 2019 at 10:30 AM, that the preventive maintenance of the Coulter Act Diff 2 system were performed daily but not recorded since January 2018. 5. The laboratory annual volume records showed that the laboratory processed the 12,397 CBC tests during the year 2018 and processed 368 patient's specimens for CBC from January 14, 2019 to July 11, 2019.

**D5469**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(10)(g)

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.

This STANDARD is not met as evidenced by:  
 Based on CBC's quality control records, laboratory annual volume record review and interview with the laboratory director on July 12, 2019 at 11:00 AM, it was determined that the laboratory failed to verify the stated value of the new lot CBC commercially assayed control materials from April 3, 2018 to November 16, 2018. The finding include : 1. On July 12, 2019 at 11:00 AM, the CBC's quality control records showed that the laboratory did not verify the following new lots of CBC control materials prior to placed in routine use: a. Lots 069300, 089300 and 079300 used from April 3, 2018 to May 24, 2018. b. Lots 069900, 079900 and 089900 used from June 14, 2018 to July 31, 2018. c. Lots 087600, 077600 and 067600 used from August 1,2018 to September 29, 2018. d. Lots 078000, 088000 and 068000 used from October 2, 2018 to November 16, 2018. 2. The laboratory director confirmed on July 12, 2019 at 11:00 AM, that the laboratory did not verify those new lots of CBC control materials prior to placed in routine. 3. The laboratory showed that the laboratory processed the 12,397 CBC tests during the year 2018.

**D5481**

**CONTROL PROCEDURES**  
 CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
 Based on CBC's quality control records review and interview with the laboratory director on July 12, 2019 at 11:20 AM, it was determined that the laboratory failed to ensure that CBC control materials values meet the laboratory's criteria for acceptability before reporting 75 out of 75 patient's specimens for CBC test results during April, 2019. The findings include: 1. The laboratory processed the CBC patients specimens by the Coulter Act Diff2 system. 2. On July 12, 2019 at 11:20 AM, the CBC's quality control records showed that the laboratory used the following lots of CBC control materials during the month April 2019: lot 079400, 069400 and 089400. However, the laboratory did not have available the quality control graph nor the control values prints-out from April 1, 2019 to April 30, 2019. 3. The laboratory director confirmed on July 12, 2019 at 11:20 AM, that the laboratory did not have available the CBC quality control record for the month of April 2019. He stated , that the quality control data were lost by the Coulter Act Diff2 system. 4. The laboratory reporting 75 out of 75 patient's specimens for CBC test results by the Coulter Act Diff2 system during April, 2019.

**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 lack of room humidity chart records for the bacteriology area, Coulter Act Diff 2 system manufacturer's instructions, preventive maintenance record, CBC's quality control records, laboratory annual volume records, personnel file records review and interview with the laboratory director on July 12, 2019 at 11:20 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system. Refer to D 6093 ( The laboratory director on July 12, 2019 at 11:20 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for the analytic system). Refer to D 6103 ( The laboratory director failed to follow the established schedule for the evaluation of the clinical consultant competence).

**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 lack of room humidity chart records for the bacteriology area, Coulter Act Diff 2 system manufacturer's instructions, preventive maintenance record, CBC's quality control records, laboratory annual volume records review and interview with the laboratory director on July 12, 2019 at 11:20 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for the analytic system. Refer to D 5024 ( The laboratory failed to meet the analytic system requirements for Hematology specialty). Refer to D 5411 ( The laboratory failed to monitor and document the room relative humidity of the bacteriology area since January 2018).

**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 personnel file records review and laboratory director interview on July 12, 2019 at 9:30 AM, it was determined that the laboratory director failed to follow the established schedule for the evaluation of the clinical consultant competence. The findings include: 1. The laboratory schedule for the clinical consultant competence evaluation showed that it must be performed every year. 2. On July 12, 2019 at 9:30

AM, the personnel file record showed that the laboratory did not perform every year the clinical consultant competence. The last competence in record was performed on July 28, 2017. 3. The laboratory director confirmed on July 12, 2019 at 9:30 AM, that the clinical consultant competence was not performed yearly.