

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0682233	(X3) Date Survey Completed 11/15/2019
Name of Provider or Supplier Laboratorio Clinico Rex	Street Address, City, State Calle 1 A5 Rexville, Bayamon, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Individualized Quality Control Plan (IQCP) in Bacteriology and interview with the testing personnel at 10:30 AM on November 15, 2019, the laboratory failed to develop complete IQCP plans for the Microscan identification system and antimicrobial sensitivity test, and culture media from January 1, 2019 to November 14, 2019. The findings included: 1. The IQCP for the Microscan Identification system, Microscan Antimicrobial Sensitivity test and culture media did not include the following requirements: a. The Risk Assessment (RA) information (potential failure modes, possible failure cause, estimate the probability that the failures would occur and estimate the probability would lead to a hazardous situation). b. The Quality Control Plan (QCP) did not have the approval signature of the laboratory director. c. The Quality Assessment (QA) section was not included. 2. The testing personnel stated at 10:30 AM on November 15, 2019, the laboratory evaluated the risk assessment of those tests during de year 2018 but did not documented the three sections of the IQCP. 3. The laboratory processed 30 pastiest specimens for Microscan identification and antimicrobial sensitivity test from January 1, 2019 to November 14, 2019.</p>

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on white blood cells (WBC) differential results comparison records (years 2017, 2018 and 2019) and testing personnel interview at 9:45 AM on November 15, 2019, it was determined that the laboratory failed to evaluate twice a year the relationship of the WBC differential results between the manual method and the Coulter JT system from October 28, 2017 to June 11, 2019. The findings include: 1. The laboratory performed the WBC differential results by two methods: manual examination and by the Coulter JT system. 2. The comparison records for the WBC differential results showed that the laboratory did not evaluate twice a year the relationship of the WBC differential results between the manual method and the Coulter JT system from October 28, 2017 to June 11, 2019. The laboratory performed the WBC differential results comparison on October 28, 2017, May 2, 2018 and June 11, 2019. 3. The testing personnel confirmed at 9:45 AM on November 15, 2019, that the laboratory did not evaluate twice a year the relationship of the WBC differential results between the manual method and the Coulter JT system from October 28, 2017 to June 11, 2019. 4. The laboratory reported the following manual WBC differential patients results: #121082 on 09/05/2018, #121322 on 10/03/2018, #121685 on 11/21/2018, #121692 on 11/21/2018, #121928 on 12/19/2018, #124617 on 11/05/2019, #124618 on 11/05/2019, #124626 on 11/06/2019, #124662 and #124673 on 11/12/2019.

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 review of Individualized Quality Control Plan (IQCP) in Bacteriology subspecialty, white blood cells (WBC) differential results comparison records (years 2017, 2018 and 2019) and interview with the testing personnel at 10:30 AM on November 15, 2019, the laboratory director failed to comply with the analytic system requirements. Refer to D 5445 (The laboratory failed to develop complete IQCP plans for the Microscan identification system and antimicrobial sensitivity test, and culture media from January 1, 2019 to November 14, 2019). Refer to D 5775 (The laboratory failed to evaluate twice a year the relationship of the WBC differential results between the manual method and the Coulter JT system from October 28, 2017 to June 11, 2019).

D6177

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on white blood cells (WBC) differential results comparison records (years 2017, 2018 and 2019) and testing personnel interview at 9:45 AM on November 15, 2019, it was determined that the testing personnel failed to follow quality control procedures from October 28, 2017 to June 11, 2019. Refer to D 5775 (The laboratory failed to evaluate twice a year the relationship of the WBC differential results between the manual method and the Coulter JT system from October 28, 2017 to June 11, 2019).