

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1097944	(X3) Date Survey Completed 03/08/2018
Name of Provider or Supplier Laboratorio Clinico Beatriz Inc	Street Address, City, State Car Pr-787 Km 4 Hm 7 Barrio Bayamon, Cidra, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on syphilis serology records review in 2016-2018 and laboratory general supervisor interview at 10:00 AM on March 8, 2018, it was determined that the laboratory failed to perform syphilis serology test as required by manufacturer's instructions by TECO method. The findings include: 1. The laboratory syphilis serology quality control were review from March 2016 to March 7, 2018. 2. The manufacturer's requires that the laboratory must perform the needle calibration, verify the rotator rpm and monitor the room temperature in the laboratory. 3. From March 2016 to March 7, 2018, the records showed that the laboratory did not document nor verify the needle calibration in RPR (Rapid plasma reagin) testing area. 4. The laboratory processed and reported two hundred thirty (230) RPR (Rapid plasma reagin) patient's samples since March 2016. 5. The laboratory general supervisor confirmed on March 8, 2018 that the laboratory failed to document nor verify the needle calibration when processes RPR to ensure that the dropping bottle and needle dispense an appropriate amount of antigen needed to perform the test.</p>
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in</p>

493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on virology quality control records review and laboratory general supervisor interview at 9:30 AM on March 8, 2018, it was determined that the laboratory did not evaluate the new lots of Influenza A-B test by Osom method for positive and negative reactivity prior to placed it in routine use. The findings include: 1. The laboratory uses Osom method for Influenza A-B patient's tests. 2. From March 2016 to March 2018, the records showed that the laboratory received and opened the following reagent kit for Influenza A-B and no evaluation of their reactivity was performed: Lot Expiration Date Opened 151468 2/2017 1/10/17 161439 3/31/18 2/14/17 161474 3/31/18 12/8/17 3. The laboratory processed and reported twenty one (21) Influenza A-B patient's samples since 2017. 4. The laboratory general supervisor confirmed on March 8, 2018, that the laboratory did not evaluate the new lots of Influenza A-B test by Osom method since 2017.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on quality assessment (QA) records review in 2016-2018 and laboratory general supervisor interview on March 8, 2018 at 10:30 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. The laboratory failed to perform syphilis serology test as required by manufacturer's instructions by TECO method. Refer to D5411. 2. The laboratory did not evaluate the new lots of Influenza A-B test by Osom method for positive and negative reactivity prior to placed it in routine use. Refer to D5471.

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 virology and syphilis serology quality control records review from March 2016 to March 2018 and laboratory general supervisor interview at 10:30 AM on March 8, 2018, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5411 and D5471.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment 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 Quality Assessment (QA) records review in 2016-2018 and laboratory general supervisor interview at 10:30 a.m. on March 8, 2018, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to D5791.

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 quality control records review in 2016-2018 and laboratory general supervisor interview on March 8, 2018 at 10:30 AM, it was determined that the general supervisor failed to follow quality control procedures. The findings include: 1. The laboratory failed to perform syphilis serology test as required by manufacturer's instructions by TECO method. Refer to D5411. 2. The laboratory did not evaluate the new lots of Influenza A-B test by Osom method for positive and negative reactivity prior to placed it in routine use. Refer to D5471.