

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0673282	(X3) Date Survey Completed 11/09/2018
Name of Provider or Supplier Laboratorio Clinico Barbosa	Street Address, City, State Ave Barbosa #315, Hato Rey, 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
D5405	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on Detector manufacturer's instructions, mononucleosis (MONO) and C reactive protein (CRP) testing records review and testing personnel interview on November 9, 2018 at 10:50 AM, it was determined that the laboratory failed to follow manufacturer's instruction when 4 patient's samples were tested and reported for negative results of Mono and CRP qualitative tests by the Detector methods from October 22, 2018 to October 28, 2018. The findings include: 1. The Detector manufacturer's instructed the laboratory to check all negative seras of CRP and Mono by retesting at 1:10 dilution due to a prozone phenomena. 2. On November 9, 2018 at 10:50 AM, the Detector /MONO testing records showed that the laboratory did not check 2 out of 2 patients specimens (negative seras) by retesting at 1:10 dilution before it reported as negative result: patient specimen #91409 on October 18, 2018 and patient specimen # 91603 on October 28, 2018. 3. On November 9, 2018 at 10:50 AM, the Detector /Crp testing records showed that the laboratory did not check 2 out of 2 patients specimens (negative seras) by retesting at 1:10 dilution before it reported as negative result: patient specimen #91496 on October 22, 2018 and patient specimen # 91376 on October 18, 2018. 4 . The testing personnel confirmed on November 9, 2018 at 10:50 AM, that the testing records showed that those specimens were not diluted.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on rheumatoid factor (RA) and C reactive protein (CRP) testing records review and testing personnel interview on November 9, 2018 at 10:50 AM, it was determined that the laboratory failed to include at least once a day, a negative and positive control materials when 2 out of 2 patients specimens were tested for CRP qualitative test and 3 out of 3 patients specimens were tested for RA qualitative tests from June 13, 2018 to December 18, 2017. The findings include: 1. On November 9, 2018 at 10:50 AM, the RA testing record showed that the laboratory did not include at least once a day, a negative and positive control materials when 3 out of 3 patients specimens were tested for RA qualitative tests from June 13, 2018 to October 28, 2018: patients specimens # 86874 and #86904 on June 13, 2018 and patient specimen # 91627 on October 28, 2018. 2. On November 9, 2018 at 10:50 AM, the CRP testing record showed that the laboratory did not include at least once a day, a negative and positive control materials when 2 out of 2 patients specimens were tested for CRP qualitative tests from December 18, 2017 to October 28, 2018: patient specimen # 80508 on December 18, 2017 and patient specimen # 91627 on October 28, 2018. 3. The testing personnel confirmed on November 9, 2018 at 10:50 AM, that the testing records of CRP and RA did not include the control procedures those days.

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 manual, quality assessment records review (2017-2018) and technical supervisor interview on November 9, 2018 12:30 PM, it was determined that the laboratory did not follow the established Quality Assessment Program to monitor and evaluate the patient tests results for inconsistencies with patient information from January 1, 2017 to November 8, 2018. The findings include: 1. The laboratory Quality Assessment manual showed that the laboratory designate a log sheet to document the patients tests results for inconsistencies with patient information. 2. The laboratory did not have quality assessment records to evaluate the patient tests results for inconsistencies with patient information from January 1, 2017 to November 8, 2018. 3. The technical supervisor confirmed that the laboratory did not document this assessment since January 2017.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on Detector manufacturer's instructions, mononucleosis (MONO), rheumatoid factor (RA) and C reactive protein (CRP) testing records review and testing personnel interview on November 9, 2018 at 10:50 AM, it was determined that technical consultant failed to comply with the requirements of the analytic systems for the general serology tests. Refer to D 5405 (The laboratory did not follow manufacturer's instruction when 4 patient's samples were tested and reported for negative results of Mono and CRP qualitative tests by the Detector methods from October 22, 2018 to October 28, 2018.) Refer to D 5449 (The laboratory did not include at least once a day, a negative and positive control materials when 2 out 2 patients specimens were tested for CRP qualitative test and 3 out 3 patients specimens were tested for RA qualitative tests from June 13, 2018 to December 18, 2017).

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on Quality Assessment manual, quality assessment records review (2017-2018) and technical supervisor interview on November 9, 2018 12:30 PM, it was determined that the laboratory director failed to ensure compliance with quality assessment requirements. Refer to D 5791 (The laboratory did not follow the established Quality Assessment Program to monitor and evaluate the patient tests results for inconsistencies with patient information from January 1, 2017 to November 8, 2018).

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
Based on Detector manufacturer's instructions, mononucleosis (MONO), rheumatoid factor (RA) and C reactive protein (CRP) testing records review and testing personnel interview on November 9, 2018 at 10:50 AM, it was determined that technical

consultant failed to ensure compliance with the requirements of the analytic systems for general serology tests. Refer to D 5405 (The laboratory did not follow manufacturer's instruction when 4 patient's samples were tested and reported for negative results of Mono and CRP qualitative tests by the Detector methods from October 22, 2018 to October 28, 2018.) Refer to D 5449 (The laboratory did not include at least once a day, a negative and positive control materials when 2 out 2 patients specimens were tested for CRP qualitative test and 3 out 3 patients specimens were tested for RA qualitative tests from June 13, 2018 to December 18, 2017).

D6072

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(3)

Each individual performing moderate 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 Detector manufacturer's instructions, mononucleosis (MONO), rheumatoid factor (RA) and C reactive protein (CRP) testing records review and testing personnel interview on November 9, 2018 at 10:50 AM, it was determined that the testing personnel failed to follow quality control procedures for the general serology tests. Refer to D 5405 (The laboratory did not follow manufacturer's instruction when 4 patient's samples were tested and reported for negative results of Mono and CRP qualitative tests by the Detector methods from October 22, 2018 to October 28, 2018.) Refer to D 5449 (The laboratory did not include at least once a day, a negative and positive control materials when 2 out 2 patients specimens were tested for CRP qualitative test and 3 out 3 patients specimens were tested for RA qualitative tests from June 13, 2018 to December 18, 2017).