

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0963573	(X3) Date Survey Completed 07/12/2018
Name of Provider or Supplier Laboratorio Clinico Melania	Street Address, City, State Carr Pr-3, Km 142, Hm 3, Sector Melania,, Guayama, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing records review in year 2018 and laboratory general supervisor interview at 11:30 AM on July 12, 2018, it was determined that the laboratory failed to lended 5 of 5 proficiency testing samples for first testing event of proficiency testing (April 2018) for general immunology and syphilis serology samples from Puerto Rico Proficiency Testing Program to Laboratorio Clinico Bristol Angeli (40D0658091) The findings include: 1. The Laboratorio Clinico Melania general supervisor stated during interview on July 12, 2018 at 11:30 AM that personnel from Laboratorio Clinico Bristol Angel requested the loan of the general immunology first testing event (year 2018) proficiency samples. 2. The Laboratorio Clinico Melania general supervisor stated that she lended the following proficiency samples to Laboratorio Clinico Bristol Angeli on May 22, 2018. a. Syphilis serology PT samples: 2018-321, 2018-322, 2018-323, 2018-324 and 2018-325. b. Rheumatoid Arthritis (RA latex), C reactive protein (CRP) and Mononucleosis (Mono) proficiency samples; 2018-351, 2018-352, 2018-353, 2018-354 and 2018-355. 3. Review of the proficiency samples intermediate work showed that the proficiency samples were processed at the Laboratorio Clinico Melania on May 8, 2018. 4. Review of the</p>

proficiency records attestation statement showed that Laboratorio Clinico Melania reported the samples results to the PTNET on May 25, 2018. Refer to D2011 and D2013.

D2011

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(3)

Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing records review in year 2018 and laboratory general supervisor interview at 11:30 AM on July 12, 2018, it was determined that the laboratory failed to lend to another laboratory. The findings include: 1.The laboratory was enrolled in the Puerto Rico Proficiency Testing Program for general immunology and syphilis serology proficiency samples. 2.The Laboratorio Clinico Melania general supervisor stated that she lended the proficiency testing samples from April 2018 (First Testing Event - syphilis serology and general immunology RPR (2018-321 to 2018-325), RA (2018-351 to 2018-355), CRP (2018-351 to 2018-355) and Monotest (2018-351 to 2018-355) to Laboratorio Clinico Bristol Angeli on May 22, 2018. 3.The laboratory general supervisor stated on July 12, 2018, that the Laboratorio Clinico Bristol Angeli returned the proficiency samples from April 2018 (First Testing Event - syphilis serology and general immunology) to Laboratorio Clinico Melania on May 28, 2018.

D2013

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

	<p>Based on review of the Puerto Rico Proficiency Testing intermediate work records review in year 2018 and laboratory general supervisor interview at 11:30 AM on July 12, 2018, it was determined that the laboratory lended tje general immunology first testing event of year 2018 to Laboratorio Clinico Bristol Angeli. The findings include: 1. The laboratory general supervisor stated that the PT samples were requested by Laboratorio Clinico Bristol Angeli on May 22, 2018. 2. The laboratory general supervisor stated on July 12, 2018, that the PT samples were returned to the laboratory on May 28, 2018. 3. The PT samples intermediate work showed that the laboratory processed their PT samples on May 8, 2018.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing records review (year 2018) and laboratory general supervisor interview at 11:30 AM on July 12, 2018, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory proficiency testing samples requirements. Refer to D6089.</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing records review (year 2018) and laboratory general supervisor interview at 11:30 AM on July 12, 2018, it was determined that the laboratory failed to prevent that proficiency testing samples were lended to another laboratory. The finding includes: 1. The laboratory general supervisor stated on July 12, 2018 at 11:30 AM, that she lended on the general immunology first testing event (year 2018) proficiency samples to Laboratorio Clinico Bristol Angeli.</p>