

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658091	(X3) Date Survey Completed 07/12/2018
Name of Provider or Supplier Express Clinical Lab	Street Address, City, State Calle Baldorioty Num 22 Oeste, 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:</p> <p>A. Based on a complaint submitted by the Puerto Rico Proficiency Testing Program, Proficiency Test Enrollment form and interview with the laboratory general supervisor from Laboratorio Clinico Bristol Angeli, it was determined that the laboratory failed to enrolled in a PT Program for year 2018. The findings include: 1. On June 12, 2018 the Puerto Rico Department of Health (PRDOH) CLIA Program received, by email, a complaint from the Puerto Rico Proficiency Testing Program (PRPTP) related to a PT referral. 2. The email from Puerto Rico Proficiency Testing Program stated that Laboratorio Clinico Bristol Angeli lended proficiency samples from another laboratory during the general immunology first testing event for year 2018. The laboratory reported the samples. However as on June 12, 2018 the Puerto Rico Proficiency Testing Program did not have Laboratorio Clinico Bristol Angeli as a participant. 3. The Puerto Rico Proficiency Testing Program submitted to the PRDOH a hand written a Test Enrollment Form from Laboratorio Clinico Bristol Angeli signed by the laboratory general supervisor on November 2, 2017. 4. The Test Enrollment Form showed in the first page a note: "Lab Closed since September 20, 2017, no power, no generator. The note include the initials of the laboratory general supervisor. 5. On the bottom of the page 1 another note was written: "Sending by paper because</p>

the lab is closed since September 20 due to Hurricane". 6. The first page also showed another hand written note from the former Puerto Rico Proficiency Testing Program director: "Did not have an explanatory letter. Is inactive in system dated 9/1/2017. 7. During interview with the lab general supervisor on July 12, 2018 at 8:30 AM she showed several emails sent to and from the Puerto Rico Proficiency Testing Program. a. March 15, 2018 (10:14 AM) - From Laboratorio Clinico Bristol Angeli to Puerto Rico Proficiency Testing Program, asking for the first testing event of year 2018. b. March 15, 2018 (11:58 AM) - From the Puerto Rico Proficiency Testing Program letting her know that the PT box containing the samples was returned to the Puerto Rico Proficiency Testing Program. That laboratory may pick up the box at the Puerto Rico Proficiency Testing Program offices. c. March 19, 2018 (7:08 AM) - From Laboratorio clinico Bristol Angeli to Puerto Rico Proficiency Testing Program. Informing the Puerto Rico Proficiency Testing Program that the returned box must be the one from December 2017 shipment when the laboratory was closed. d. May 9, 2018 - several emails sent to Puerto Rico Proficiency Testing Program asking for the samples of the general immunology first testing event. 8. The Puerto Rico Proficiency Testing Program submitted a letter to the Puerto Rico Department of Health (PRDOH) CLIA Program from Laboratorio Clinico Bristol Angeli in which the laboratory announced that they were offering services. The letter was dated on June 11, 2018. The letter included a hand written note done by the Puerto Rico Proficiency Testing Program "reactivation processed on 6/12/2018 (June 12, 2018). Must enroll in PTNET. 9. The laboratory general supervisor on July 12, 2018 confirmed that she enrolled in Puerto Rico Proficiency Testing Program but she did not have evidence of the enrollment. B. Based on a complaint submitted by the Puerto Rico Proficiency Testing Program and interview with the laboratory general supervisor on July 12, 2018 at 8:30 AM, it was determined that the laboratory reported PT results using PT samples from another laboratory. The findings include: 1. On June 12, 2018 the Puerto Rico Department of Health (PRDOH) CLIA Program received, by email, a complaint from the Puerto Rico Proficiency Testing Program (PRPTP). The complaint stated that Laboratorio Clinico Bristol Angeli processed and reported PT samples borrowed by another laboratory. 2. The complaint also stated that the information was given to the Puerto Rico Proficiency Testing Program by the laboratory general supervisor on June 12, 2018. 3. During the complaint investigation on July 12, 2018 at 8:30 AM the laboratory general supervisor stated that due to the fact that they did not received the PT samples she decided to ask Laboratorio Clinico Melania to borrow her the general immunology first event PT samples. 4. The laboratory general supervisor stated that the report submitted in the PTNET system were the results processed by her in Laboratorio Clinico Bristol Angeli with the PT samples from Laboratorio Clinico Melania

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 proficiency records review (year 2018) and laboratory general supervisor interview at 8:30 AM on July 12, 2018, it was determined that the Laboratorio Clínico Bristol Angeli processed and reported proficiency testing samples for the year 2018, first general immunology testing event, that were borrowed from another laboratory. The findings include: 1. During interview on July 12, 2018 at 8:30 AM with the Laboratorio Clínico Bristol Angeli general supervisor stated that she borrowed the proficiency samples from Laboratorio Clínico Melania (40D0963573) because she did not received the samples from the Puerto Rico Proficiency Testing Program 2. On May 22, 2018, the Laboratorio Clínico Bristol went to Laboratorio Clínico Melania for requesting proficiency samples from April 2018 (First Testing Event - syphilis serology and general immunology). 3. The laboratory general supervisor stated on July 12, 2018 at 8:30 AM that the laboratory processed and reported the proficiency 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) on May 22, 2018. 4. Among the PT records reviewed during the complaint investigation visit the laboratory general supervisor showed the attestation statement for the first testing event dated on May 22, 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:
Based on proficiency records review (year 2018) and laboratory general supervisor interview at 8:30 AM on July 12, 2018, it was determined that the laboratory processed and reported PT samples from another laboratory. The findings include: 1. The laboratory general supervisor stated during the interview that the following PT samples were borrowed from Laboratorio Clínico Melania on May 22, 2018: a. syphilis serology PT samples event - syphilis serology 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. 2. The laboratory general supervisor stated that the samples were processed and reported in the Puerto Rico Proficiency Testing Program

by PTNET on May 22, 2018. 4. The PT Attestation Statement showed that the reports were submitted on May 22, 2018. The laboratory general supervisor showed the Attestation statement for the testing event.

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 proficiency testing records review in 2018 and laboratory general supervisor interview at 8:30 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. The finding includes: 1. The laboratory director did not ensure the enrollment in the Puerto Rico Proficiency Testing Program. Refer to D6088. 2. The laboratory processed and reported PT samples borrowed from another laboratory. Refer to D6089.

D6088

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)

The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on a complaint submitted by the Puerto Rico Proficiency Testing Program, Proficiency Test Enrollment Form and interview with the laboratory general supervisor from the Laboratorio Clinico Bristol Angeli on July 12, 2018 at 8:30 AM, it was determined that the laboratory director did not enroll the Laboratorio Clinico Bristol Angeli in any Proficiency Testing Program for year 2018. The findings include: 1. The laboratory was enrolled in the Puerto Rico Proficiency Testing Program for all the analytes and test performed by the laboratory during years 2016 and 2017. 2. The laboratory director did not ensure the enrollment in the Puerto Rico Proficiency Testing Program before reporting borrowed samples from another laboratory during the general immunology first testing event of year 2018. 3. The general supervisor stated during interview on July 2018 at 8:30 AM that the the laboratory was already enrolled in the Puerto Rico Proficiency Program. 4. The laboratory general supervisor stated on July 12, 2018 that she did not have evidence of enrollment.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
Based on proficiency testing records review in year 2018 and laboratory general

supervisor interview at 8:30 AM on July 12, 2018, it was determined that the laboratory processed and reported PT samples borrowed by another laboratory. The findings include: 1. During the interview the laboratory general supervisor stated that she did not received the samples for the first events of year 2018 and she decided to borrow the PT samples for general immunology and syphilis serology to processed and reported them in the PTNET system on May 22, 2018. 2. REview of the Proficiency testing records, Attestation statement showed that the samples results were submitted on May 22, 2018.