

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1000674	(X3) Date Survey Completed 03/28/2019
Name of Provider or Supplier Laboratorio Clinico Fair View Csp	Street Address, City, State Carr Pr-845, D-32, Urb Fair View, Trujillo Alto, 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 Puerto Rico Proficiency Testing Program (PRPTP) records review (years 2017 - 2018), Puerto Rico Laboratory Division Proficiency Testing desk review and laboratory general supervisor interview on March 28, 2019 at 9:45 AM, it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for hematology white blood cell (WBC) three part differential since January 2017. The findings includes: 1. The laboratory was enrolled only in the Puerto Rico Proficiency Testing Program in 2017 and 2018. 2. The laboratory uses a Sysmex K4500 system to perform hematology patient samples tests. 3. The Puerto Rico Proficiency Testing records were reviewed from years 2017 to 2018, showing that the laboratory failed to enroll and participate in proficiency testing for hematology white blood cell (WBC) three part differential. 4. The general supervisor confirmed that the laboratory failed to participate in proficiency testing for hematology white blood cell (WBC) three part differential in years 2017 and 2018. He also stated that the laboratory was enrolled in the Medical Laboratory Evaluation (MLE) proficiency program on September 28, 2018, for the proficiency testing program year 2019. 5. The laboratory processed and reported 10,855 patients specimens for hematology from January 2, 2018 to December 31, 2018.</p>

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 Puerto Rico Proficiency Testing Program (PRPTP) records review from January 2017 to December 2018 and laboratory general supervisor interview on March 28, 2019 at 9:45 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the proficiency testing requirements. The findings include: 1. The laboratory director failed to enroll in an HHS approved proficiency testing program for the hematology white blood cell (WBC) three part differential since January 2017. Refer to D6088.

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 Puerto Rico Proficiency Testing Program records review and laboratory general supervisor interview on March 28, 2019 at 9:45 AM, it was determined that the laboratory director failed to ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the white blood cell (WBC) three parameters differential since January 2017. The findings include: 1. The laboratory processed and reported patients specimens for the WBC three parameters differential results since January 2017, however the laboratory is not enroll in a an HHS-approved proficiency testing program for this tests. Refer to D 2000. 2. The general supervisor confirmed on March 28, 2019 at 9:45 AM, that the laboratory did not enroll in an approved proficiency program for the WBC three parameters differential testing since January 2017. He also stated, that the laboratory was enrolled in the Medical Laboratory Evaluation Proficiency Testing Program on September 28, 2018.