

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0693037	(X3) Date Survey Completed 10/11/2019
Name of Provider or Supplier Laboratorio Clinico Tintillo	Street Address, City, State Ave Buen Samaritano #12 A Bo J Domingo, Guaynabo, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on Orasure Flu A&B manufacturer's instructions, Influenza A&B tests reports records (year 2019) review and laboratory director interview on October 11, 2019 at 9:30 AM, it was determined that the laboratory failed to follow manufacturer's instruction for report information when 59 out of 59 patients specimens were reported for Influenza A&B tests by Orasure method from January 9,2019 to October 9, 2019. The findings include: 1 The laboratory uses the Orasure method to detect the Influenza A&B antigen as Waived complexity. 2. Orasure manufacturer's instructions for the intended uses establish that the negative test results are presumptive it is recommended this results be confirmed by viral culture. 3. On October 11, 2019 at 9:30 AM, the Influenza A&B tests reports records showed that the laboratory did not include the manufacturer required information. The laboratory reported the negative Influenza A or B results as final negative results. 4. The laboratory director confirmed on October 11, 2019 at 9:30 AM, that the Influenza A&B tests reports did not include the required information. 5. The laboratory reported 59 out of 59 patients specimens for Influenza A&B tests by Orasure method from January 9,2019 to October 9, 2019.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the</p>

manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on T 890 system manufacturer's instructions, T 890 system calibration records (year 2019) review and laboratory director interview on October 11, 2019 at 10:00 AM, it was determined that the laboratory failed to verify quarterly the calibration of the T 890 system from January 2018 to October 11, 2019 when 4,635 patients specimens were processed and reported for complete cells count (CBC) tests. The findings include: 1. The laboratory processed the CBC tests by the T 890 system. 2. The T 890 system's manufacturer instructed the laboratory to verify calibration quarterly. 3. On October 11, 2019 at 10:00 AM, the calibration records of the T 890 system showed that the laboratory performed the calibration on February 27, 2019 during the year 2019. 4. The laboratory did not have available the calibration records of the T 890 system for the year 2018. 5. The laboratory director stated that the laboratory performed annually the calibration of the T 890 system during years 2018 and 2019. She confirmed that the calibration records of the T 890 system for the year 2018 were not available. 6. The laboratory processed and reported 4,635 CBC patients specimens by the T 890 system from January 2018 to October 11, 2019.

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 T 890 system manufacturer's instructions, T 890 system calibration records (year 2019) review and laboratory director interview on October 11, 2019 at 10:00 AM, it was determined that the laboratory director failed to comply with the analytic requirements for the CBC tests. Refer to D 5437 (The laboratory did not verify quarterly the calibration of the T 890 system from January 2018 to October 11, 2019 when 4,635 patients specimens were processed and reported for CBC tests).