

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0697546	(X3) Date Survey Completed 11/22/2023
Name of Provider or Supplier Lab Clinico Exp Trujillo Alto	Street Address, City, State Ave Fronteras G-I-B Expreso Trujillo Alto, Rio Piedras, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on syphilis serology quality control and patient test worksheet records, manufacturer's instructions review, and laboratory director interview, on November 22, 2023 at 11:00 AM, it was determined that the laboratory failed to follow the manufacturer's instructions for the syphilis serology tests, when 2 out of 2 patient specimens were tested on November 22, 2023. The findings include: 1. The laboratory uses the ASI's reagent kit to perform patient syphilis serology test. Review of the ASI's manufacturer's instructions on November 22, 2023 at 10:43 AM, showed that the laboratory must remove and wash the needle at the end of the day. 2. On November 22, 2023 at 10:40 AM, the syphilis serology quality control and patient test worksheet records were reviewed. The records showed that the laboratory did not perform the needle wash as required by the manufacturer, when they processed and reported 2 out of 2 patient specimens on November 22, 2023. 3. The laboratory director confirmed on November 22, 2023 at 11:00 AM, that the laboratory did not follow the manufacturer's instructions related to the needle wash, on November 22, 2023.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

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 Syphilis Serology (Rapid Plasma Reagin (RPR)) quality control records review (years 2022 to 2023) and interview with the laboratory director and testing personnel on November 22, 2023 at 11:00 AM, it was determined that the laboratory did not include each day of testing the reactive nor the non reactive control materials when 2 out of 2 patients specimens were tested and reported for RPR on November 16, 2023. The findings include: 1. The laboratory use ASI RPR Card testing method to perform the Syphilis qualitative test. 2. On November 22, 2023 at 10:40 AM, the syphilis quality control record was review and showed that the laboratory did not include each day of testing the reactive nor the non reactive control materials on November 16, 2023. 3. The laboratory director and the testing personnel confirmed on November 22, 2023 at 11:00 AM, that the laboratory failed to include each day of patient testing the reactive and non reactive control material the following day 11/16 /2023. 4. The laboratory processed and reported 2 out of 2 patient samples for Syphilis (RPR) qualitative tests without controls on November 22, 2023.

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 quality control records review of RPR Tests (rapid reagin plasma), year 2022 and 2023 and interview with the laboratory director on November 22, 2023 at 11:00 AM, it was determined that the laboratory director failed to ensure the compliance with the quality control program. Refer to D5411 and D5449.