

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0677191	(X3) Date Survey Completed 07/10/2024
Name of Provider or Supplier Laboratorio Clinico Alhambra	Street Address, City, State Calle Comercio #104, Juana Diaz, 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at LABORATORIO CLINICO ALHAMBRA on July 10, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following condition level deficiencies were found during the unannounced routine CLIA recertification survey ending on July 10, 2024.
D5012	<p>SYPHILIS SEROLOGY CFR(s): 493.1207</p> <p>If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on manufacturer's instructions, syphilis serology quality control records, patient's reports worksheets review (years 2023-2024) and laboratory general supervisor interview on July 10, 2024 at 10:35AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphilis serology tests. Refer to D 5405 and D5411.</p>
D5405	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on manufacturer's instructions, syphilis serology quality control records, patient's reports worksheets review (years 2023-2024) and laboratory general supervisor interview on July 10, 2024 at 10:35AM, it was determined that the laboratory failed to follow the manufacturer's instructions when reported and performed 142 out of 820 syphilis serology patient's samples by Aim Rapid plasma reagin (RPR) method in 31 out of 132 days since January 2, 2024. The findings include: 1. The laboratory uses Aim Rapid plasma reagin (RPR) method when patient's specimen were tested for syphilis serology since January 2024. Reviewed on July 10, 2024 at 10:35AM. 2. The manufacturer's instructions establishes that three levels of control material (non-reactive, minimal to moderate and reactive) must be included each day of testing. Reviewed on July 10, 2024 at 10:40AM. 3. From January 2, 2023 to July 9, 2024 (31 days), the syphilis serology quality control records and the patient's reports worksheet showed that the laboratory did not include the three levels of control material when it processed and reported 142 out of 820 patient's specimens for syphilis serology by Aim RPR method. Reviewed on July 10, 2024 at 10:45AM. 4. The laboratory general supervisor stated on July 10, 2024 at 10:55AM that the laboratory did not include the three levels of control material when it processed and reported patients specimens for syphilis serology by Aim RPR method those days.

D5411

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)**

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.

This STANDARD is not met as evidenced by:
Based on manufacturer's instructions, syphilis serology quality control records, patient's reports worksheets review (years 2023-2024) and laboratory general supervisor interview on February 8, 2023 at 10:35AM, it was determined that the laboratory failed to perform syphilis serology test as required by the manufacturer's instructions when reported and performed 142 out of 820 syphilis serology patient's samples by Aim Rapid plasma reagin (RPR) method in 31 out of 132 days. The findings include: 1. The laboratory uses Aim Rapid plasma reagin (RPR) method to perform RPR (rapid plasma reagin) syphilis serology patient's samples tests. Reviewed on July 10, 2024 at 10:35AM. 2. The manufacturer requires that the laboratory must perform the needle calibration and must211 be removed after each day of testing, rinsed with distilled water, and allowed to air dry. In addition, the laboratory should be adjusted and verify the mechanical rotator at 100 5 rpm for eight (8) minutes and monitor the room temperature (20 to 30 C) in the laboratory. Reviewed on July 10, 2024 at 10:40AM. 3. From January 2, 2024 to July 9, 2024 (31 days), the syphilis serology quality control records showed that the laboratory did not did not document nor verify the needle calibration, needle clean, rotator rpm or the room temperature monitoring in the RPR (Rapid plasma reagin) testing area in the following days: Reviewed on July 10, 2024 at 10:45AM. Date #samples 1/2/2024 3 1 /4/2024 1 1/5/2024 2 1/10/2024 9 1/13/2024 3 1/15/2024 1 1/17/2024 4 1/19/2024 3 1 /23/2024 11 1/27/2024 3 2/1/2024 1 2/5/2024 2 2/7/2024 5 2/10/2024 5 2/15/2024 2 2 /23/2024 4 3/2/2024 1 3/5/2024 6 3/12/2024 1 3/16/2024 2 3/22/2024 1 3/27/2024 1 4 /5/2024 4 4/11/2024 2 4/18/2024 2 4/29/2024 9 5/7/2024 3 5/25/2024 2 6/6/2024 1 6 /26/2024 3 7/8/2024 8 4. The laboratory processed and reported one hundred forty two

	<p>(142) RPR (Rapid plasma reagin) patient's samples tests those days. Reviewed on July 10, 2024 at 10:45 AM. 5. The laboratory general supervisor stated on July 10, 2024 at 10:55AM, that the laboratory did not document nor verify the needle calibration, clean needle, rotator rpm nor the room temperature monitoring in the RPR (Rapid plasma reagin) testing area those days.</p>
<p>D5445</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the urinalysis quality control records review (years 2023-2024) and laboratory general supervisor interview on July 10, 2024 at 9:45 AM, it was determined that the laboratory did not include or document a negative microscopic control material for manual microscopic urinalysis examinations, when 4,048 (in year, 2023) and 2,235 (in year 2024) patients were processed and reported from January 2, 2023 to July 9, 2024. The findings include: 1. The urinalysis quality control records were reviewed on July 10, 2024 at 9:45 AM. 2. The recoesds showed that the laboratory did not include or document a negative control material for urinalysis microscopy test. Reviewed on July 10, 2024 at 9:45 AM. 3. The laboratory director confirmed on July 10, 2024 at 10:00 AM, that no negative microscopy control was implemented from January 2, 2023 to July 9, 2024, when when 4,048 (in year,2023) and 2,235 (in year 2024) patients were processed and reported.</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 manufacturer's instructions, syphilis serology quality control records, patient's reports worksheets review (years 2023-2024) and laboratory general supervisor interview on July 10, 2024 at 10:35AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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</p>

failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on manufacturer's instructions, syphilis serology and urinalysis quality control records, patient's reports worksheets review (years 2023-2024) and laboratory general supervisor interview on July 10, 2024 at 10:35AM, it was determined that the director failed to ensure the compliance with the quality control program, manufacturer's instructions when reported and performed 142 out of 820 syphilis serology patient's samples by Aim Rapid plasma reagin (RPR) method in 31 out of 132 days since January 2, 2024 and did not include or document a negative microscopic control material for manual microscopic urinalysis examinations, when 4,048 (in year 2023) and 2,235 (in year 2024) patients were processed and reported from January 2, 2023 to July 9, 2024.. Refer to D5405, D5411 and D5445.

D6144

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:
Based on manufacturer's instructions, syphilis serology quality control records, patient's reports worksheets review (years 2023-2024) and laboratory general supervisor interview on July 10, 2024 at 10:35AM, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. Refer to D5405, D5411 and D5445.

D6177

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on manufacturer's instructions, syphilis serology quality control records, patient's reports worksheets review (years 2023-2024) and laboratory general supervisor interview on July 10, 2024 at 10:35AM, it was determined that the that testing personnel failed to follow quality control procedures, manufacturer's instructions when reported and performed 142 out of 820 syphilis serology patient's samples by Aim Rapid plasma reagin (RPR) method in 31 out of 132 days since January 2, 2024 and did not include or document a negative microscopic control material for manual microscopic urinalysis examinations, when 4,048 (in year 2023) and 2,235 (in year 2024) patients were processed and reported from January 2, 2023 to July 9, 2024.. Refer to D5405, D5411 and D5445.