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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D0883986 | (X3) Date Survey Completed 03/19/2025 |
| Name of Provider or Supplier Lab Clinico Punta Santiago | Street Address, City, State Calle Aduana 1, Bo Punta Santiago, Humacao, 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 |
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| D0000 | The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Punta Santiago on March 19, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on March 19, 2025. |
| D5469 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10) (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.</p> <p>This STANDARD is not met as evidenced by: A. Based on hematology quality control records review and laboratory director interview on March 19, 2025 at 10:48 AM, it was determined that the laboratory failed to verify the stated value of the new lot of control materials, when the laboratory processed and reported 324 Complete Blood Count (CBC) patient samples from January 1, 2024 to March 5, 2024. The findings include: 1. The laboratory performs hematology CBC tests with the Beckman Coulter Ac.T 5 Diff CP system. 2. The hematology quality control records reviewed on March 19, 2025 at 10:48 AM, from January 1, 2024 to March 5, 2024, showed that there was no evaluation of the manufacturer's stated values for the lot numbers 380124 (high control level), 370124 (normal control level), and 360124 (low control level) prior to placing them in routine</p> |

use on January 1, 2024. 3. The laboratory director stated on March 19, 2025 at 10:48 AM, that no evaluations of the stated lots of control materials were performed prior to placing them in routine use. 4. The laboratory director confirmed on March 19, 2025 at 10:53 AM, that the laboratory failed to evaluate the stated value of the new lot of control materials for hematology CBC tests performed by the Beckman Coulter Ac.T 5 Diff CP system, when they processed and reported 324 patient samples from from January 1, 2024 to March 5, 2024. B. Based on chemistry quality control records review and laboratory director interview on March 19, 2025 at 12:00 PM, it was determined that the laboratory failed to verify the stated value of the new lot of control materials, when the laboratory processed and reported 500 Complete Metabolic Panel (CMP) patient samples from January 1, 2024 to May 31, 2024. The findings include: 1. The laboratory performs chemistry CMP tests with the Randox Daytona RX system. 2. The chemistry quality control records reviewed on March 19, 2025 at 12:00 PM, from January 1, 2024 to May 31, 2024, showed that there was no evaluation of the manufacturer's stated values for the lot numbers 1534UN (normal control level), and 534UE (abnormal control level) prior to placing them in routine use on January 1, 2024. 3. The laboratory director stated on March 19, 2025 at 12:00 PM, that no evaluations of the stated lots of control materials were performed prior to placing them in routine use. 4. The laboratory director confirmed on March 19, 2025 at 12:05 PM, that the laboratory failed to evaluate the stated value of the new lot of control materials for chemistry CMP tests performed by the Randox Daytona RX system, when they processed and reported 500 patient samples from from January 1, 2024 to May 31, 2024.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:
Based on review of the hematology and chemistry quality control records, and interview with the laboratory director on March 19, 2025 at 12:05 PM; it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the hematology and chemistry quality control requirements. Refer to D5469.