

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>40D2103412</p>	<p>(X3) Date Survey Completed</p> <p>09/06/2024</p>
<p>Name of Provider or Supplier</p> <p>Laboratorio Neoclinico</p>	<p>Street Address, City, State</p> <p>Carr, Pr -2, Km 18, Hm 9, Comunidad Macun, Toa Baja, PR</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D3037</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing records (2023-2024) and laboratory testing personnel interview on September 6, 2024 at 9:30 A.M., it was determined that the laboratory failed to retain proficiency testing records for at least 2 years. The findings include: 1. Puerto Rico Proficiency Testing records were reviewed from February 2023 to August 2024. (review on September 6, 2024 at 9:30 a.m.) 2. The laboratory did not have available documentation (results print outs reported) from the following testing events: second testing event 2023 and second testing event 2024 - special test performed by Access . third testing event 2023- hematology test (complete blood cell) 3. The laboratory testing personnel confirmed on september 6, 2024 at 9:45 A.M. , that the laboratory did not have available the Proficiency Testing print out results from those testing events performed in 2023 and 2024.</p>
<p>D5020</p>	<p>ENDOCRINOLOGY CFR(s): 493.1212</p> <p>If the laboratory provides services in the subspecialty of Endocrinology, 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 endocrinology quality control records review (2023-2024) and interview with the laboratory testing personnel on September 6, 2024 at 12:00 P.M., it was</p>

determined that the laboratory failed to ensure compliance with the analytic system requirements for Endocrinology test. Refer D5405.

D5405

PROCEDURE MANUAL
CFR(s): 493.1251(c)

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.

This STANDARD is not met as evidenced by:
Based on manufacturer's instruction and endocrinology quality control records review year 2023-2024 and laboratory testing personnel interview on September 6, 2024 at 10:20 a.m., it was determined that the laboratory failed to follow manufacturer's instructions when patient specimens were tested for endocrinology chemistry tests by the Access 2 system. The findings include: 1. The laboratory uses Access 2 system to perform the following endocrinology patient tests: Thyroid stimulating hormone (TSH), T-uptake, free T4, free T3, Total T4, B12 vitamin, Follicle stimulating hormone (FSH), luteinizing hormone (LH), testosterone, prostate specific antigen (PSA), carcinoembryonic antigen (CEA), Vitamin D. 2. The manufacturer establishes that two levels of control material (normal and high) must be included each day of testing. 3. Review of endocrinology quality control records from January 2023 to August 2024, showed that the laboratory did not include the two levels of controls since February 1, 2024 for the following tests: Thyroid stimulating hormone (TSH), T-uptake, free T4, T4, B12 vitamin, Follicle stimulating hormone (FSH), luteinizing hormone (LH), testosterone, prostate specific antigen (PSA),Vitamin D. 4. The laboratory processed and reported 2.970 endocrinology analytes during those days. 5. Review of endocrinology quality control records from January 2023 to August 2024, showed that the laboratory did not include the two levels of controls for the following test: carcinoembryonic antigen (CEA) since June 2024 and free T4 since July 1, 2024. 6. The laboratory processed and reported 74 CEA samples test and 37 free T4 samples tests since June 2024 and July 1, 2024,, respectively. 7. The laboratory testing personnel confirmed on September 6, 2024 at 10:40 A.M.that the laboratory failed to follow manufacturer's instructions (regarding testing of control materials) when patient specimens were tested for endocrinology tests by the Access system.

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 endocrinology quality control records review (year 2023-2024) and laboratory testing personnel interview on September 6, 2024 at 12:15 P.M., 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 D 6093.

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 endocrinology quality control records review (2023-2024), it was determined that the laboratory director did not ensure that quality control procedures related to endocrinology quality control procedures were performed as established by the manufacturer's instructions. Refer to D5405.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on personnel records review and testing personnel interview on September 6, 2024 at 9:15A.M., it was determined that the laboratory director failed to ensure that the new testing personnel, prior to testing patients' specimens have the appropriate training. The finding includes: 1. The laboratory hired a new testing personnel (laboratory owner) in January 2024. This testing personnel processed and reported patients specimens in the following areas: hematology, urinalysis, endocrinology, chemistry special tests, syphilis and general serology. However, the personnel records did not include the documented training.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of personnel records files and interview with the laboratory testing personnel on September 6, 2024 at 9:00 AM, it was determined that the laboratory director did not include the written duties of the laboratory director, technical supervisor, technical consultant and general supervisor. The finding includes: 1. The laboratory personnel files were reviewed on September 6, 2024 at 9:00 AM 2. During interview with the testing personnel stated that the personnel designated as technical supervisor, technical consultant and general supervisor was the laboratory director. 3.

Review of the laboratory director file record at 9:10 A.M., showed that no written duties were included.

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 and endocrinology quality control records review (years 2023-2024) and laboratory testing personnel interview on September 6, 2024 at 12:15 P.M., it was determined that the testing personnel failed to follow manufacturer's instructions when patient specimens were tested for endocrinology chemistry tests by the Access 2 system. Refer to D5405.