

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2042950	(X3) Date Survey Completed 09/04/2024
Name of Provider or Supplier Centro De Diagnostico Y Tratamiento De Anasco	Street Address, City, State Road 402, Km 1 ,Hm 8, Barrio Marias, Anasco, 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
D3039	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) records (year 2023) and laboratory director interview on September 4, 2024, at 11:00 A.M., it was determined that the laboratory failed to maintain the Quality Assessment Program documentation; used to monitor and evaluate the laboratory activities (general system, pre-analytic, analytic and post-analytic systems) for at least 2 years. The findings include: 1. On September 4, 2024, at 11:00 A.M., the QA program evaluation was requested. The QA Program evaluation was not available. The last documentation dated from December 2022. 2. The laboratory director confirmed on September 4, 2024, at 11:45 A.M., that the laboratory did not have available the Quality Assessment documentation in the laboratory.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Quality Assessment (QA) records (year 2023) and laboratory general supervisor interview on September 4, 2024, at 11:00 A.M., it was determined</p>

that laboratory failed to evaluate and monitor the requirements for General laboratory systems. The findings include: 1. On September 4, 2024, at 11:00 A.M. the laboratory general system QA year 2023 was requested. The laboratory General systems QA record of the year 2023 was not available for evaluation. 2. In the year 2023, the laboratory failed to evaluate and monitor the requirements of laboratory General systems: patient confidentiality, specimen identification and integrity, complaint investigation, communication and personnel competency. (Reviewed on September 4, 2024, at 11:05 A.M.) 3. The laboratory director confirmed on September 4, 2024, at 11:45 A.M., that the laboratory QA General systems records were not evaluated and monitored during the year 2023.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:
Based on the lack of the Quality Assessment (QA) records (year 2023) and laboratory general supervisor interview on September 4, 2024, at 11:10 A.M., it was determined that the laboratory failed to evaluate and monitor the requirement for Pre-Analytic systems. The findings include: 1. On September 4, 2024, at 11:10 A.M., the laboratory Pre-Analytic systems QA record was requested. The Pre-Analytic systems QA record of the year 2023 was not available for evaluation. 2. In the year 2023, the laboratory failed to evaluate and monitor the requirements of Pre-Analytic systems: test request, specimen submission and handling, specimen referral. (Reviewed on September 4, 2024, at 11:15 A.M.) 3. The laboratory director confirmed on September 4, 2024, at 11:45 A.M., that the QA Pre-Analytic System records were not evaluated and monitored during the year 2023.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on lack of the Quality Assessment (QA) records (year 2023) and laboratory general supervisor interview on September 4, 2024, at 11:20 A.M., it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirement for Analytic systems. The findings include: 1. On September 4, 2024, at 11:20 A.M., the laboratory analytic QA record was requested. The Analytic system QA record of the year 2023 was not available for evaluation. 2. In the year 2023, the laboratory failed to evaluate the requirements of Analytic systems: test procedures, accurate and reliable test system, equipment, instruments, reagents, materials, specimen and reagent storage conditions, system maintenance and function checks, verification of method performance specifications, calibration, control procedures, comparison of test results, test records, corrective actions. (Reviewed on September

4,2024, at 11:25 A.M.) 3. The laboratory director confirmed on September 4, 2024, at 11:45 A.M., that the Analytic QA records were not evaluated and monitored during the year 2023.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on the lack of the Quality Assessment (QA) records (year 2023) and laboratory general supervisor interview on September 4, 2024, at 11:30 A.M., it was determined that the laboratory failed to evaluate and monitor the requirements for Post Analytic systems. The findings include: 1. On September 4, 2024, at 11:30 A.M., the laboratory post analytic QA record was requested. The post analytic system QA record of the year 2023 was not available for evaluation. 2. In the year 2023, the laboratory failed to evaluate and monitor the requirements of post analytic systems: the turn around time and the patient's final test reports. (Reviewed on September 4,2024, at 11:35 A.M.) 3. The laboratory director confirmed on September 4, 2024, at 11:45 A.M., that the post analytic QA records were not evaluated and monitored during the year 2023.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on lack of the Quality Assessment (QA) records and interview with the laboratory director on September 4, 2024, at 11: 45 A.M., it was determined that the laboratory director failed to ensure the compliance with QA requirements year 2023. Refer to D5291, D5391, D5791 and D5891.