

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0701566	(X3) Date Survey Completed 09/17/2024
Name of Provider or Supplier Laboratorio De Patologia Dr Noy Inc	Street Address, City, State 239 Avenida Arterial Hostos Suite 1a (Sotano), San Juan, 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 de Patologia Dr. Noy Inc. on September 17, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on September 17, 2024.
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review (year 2023-2024) and laboratory testing personnel interview on September 17,2024 at 12:00 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to evaluate the requirement for pre- analytic system: test request. The findings include: 1. On September 17, 2024 at 12:00 P.M., the QA records was requested. 2. The Pre-analytic system QA record showed that evaluations to test request must be performed quaterly. The laboratory did not evaluate the test request since of year 2023. (Reviewed on September 17,2024 at 12:10 PM) 3. The QA record was reviewed with the laboratory testing personnel (#9) and confirmed, during interview on Septiembre 17,2024 at 12:15 PM, that the Pre-analytic system QA records were not evaluated since of year 2023.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on Quality Assessment (QA) records review (year 2023-2024) and laboratory testing personnel interview on September 17,2024 at 12:45 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to evaluate the requirement for Post- Analytic system: Turn around times (TAT). The findings include: 1. On September 17, 2024 at 12:00 P.M., the QA records was requested. 2. The Post- analytic system QA record showed that evaluations to TAT must be performed annually. The laboratory did not evaluate the TAT in the year 2023. (Reviewed on September 17,2024 at 12:45 PM) 3. The QA record was reviewed with the laboratory testing personnel (#9) and confirmed, during interview on Septiembre 17,2024 at 12:56 PM, that the Post- analytic system QA records were not evaluated in the year 2023

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment 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 the QA records and interview with the laboratory testing personnel (#9) on September 17, 2024, at 1: 00 PM., it was determined that the laboratory director failed to ensure the compliance with QA requirements (years 2023 - 2024): test request and TAT. Refer to D5391 and D5891.