Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0701566	10/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio De Patologia Dr Noy Inc	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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Ventana HE 600 preventive maintenance and interview with the Histotechnologist #1, it was found that the laboratory did not perform the monthly nor the trimester preventive maintenance as required by the manufacturer's. The findings include: a. The laboratory used the Ventana HE 600 to perform histopathology special stains. b. The manufacturer's instructed the laboratory to perform a monthly and a trimester preventive maintenance's. c. Review of the monthly and trimester preventive maintenance (years 2017 to 2018) on October 12, 2018 at 9:40 am, showed the following: i. The laboratory did not perform the monthly preventive maintenance in: February 2017, April 2017, June 2017, July 2017, September 2017, October 2017, January 2018, February 2018, March 2018, April 2018, May 218, June 2018, July 2018, August 2018 and September 2018. ii. The laboratory only performed the trimester preventive maintenance in the first trimester of 2017. d. The Histotechnologist # 1 stated that preventive maintenance were not performed. e. The laboratory processed 6,219 special stain slides since January 2017.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

	This STANDARD is not met as evidenced by: Based on review of cytotechnologists workload reassessment records and interview with the supervisor on October 12, 2018 at 11:00 am, it was found that the laboratory did not perform the every 6 months reassessment evaluations of the cytotechnologists (CT) for year 2018. The findings include: a. The supervisor stated that the reassessment evaluations must be done in January and July of each year. b. Review if the personnel records showed that the laboratory did not perform the reassessment work load evaluations during the year 2018 of the following cytotechnologists: CT 1, CT2, CT3, CT4, CT5, CT6, CT7, CT8,CT9, CT10 AND CT12.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on review of cytotechnologists records and interview with the laboratory supervisor on October 12, 2018 at 11:00 AM, it was found that the technical supervisor did not reassess the workload limits during year 2018. Refer to D5637