Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2039051	09/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Roberto Davila -De Pedro	525 F D Roosevelt Las Americas Tower, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment Program and physician office laboratory (POL) director interview on September 24, 2020 at 11:20 AM, it was determined that the POL failed to establish and follow a Quality Assessment Program to monitor the general laboratory systems requirements (specimen identification and integrity) since January 2019. The annual volumes records showed that the POL examined and reported 200 Mohs cases during January 2019. The findings include: 1. The POL did not have a Quality Assessment Program to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirement since January 2019: specimen identification and integrity. 2. The annual volumes records showed that the POL examined and reported 200 Mohs cases during January 2019. 3. The POL director confirmed on September 24, 2020 at 11:20 AM, that the POL did not establish a Quality Assessment Program to assess the general laboratory system for the specimen identification and integrity since January 2019.
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 lack of Quality Assessment Program, lack of quality assessment records and physician office laboratory (POL) director interview on September 24, 2020 at 11:20 AM, it was determined that the POL failed to establish and follow a Quality Assessment Program to monitor the following requirements of the preanalytic system: specimen handling and specimen referrals since January 2019. The annual volumes records showed that the POL examined and reported 200 Mohs cases during January 2019. The findings include: 1. The POL did not have a Quality Assessment Program to monitor the following requirements of the preanalytic systems: specimen handling (collection, labeling, processing, storage) and specimen referrals(biopsis) since January 2019. 2. The annual volumes records showed that the POL examined and reported 200 Mohs cases during January 2019. 3. The POL director confirmed on September 24, 2020 at 11:20 AM, that the POL did not have available a Quality Assessment Program to monitor the preanalytic system since January 2019.
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 Quality Assessment Program, lack of quality assessment records and physician office laboratory (POL) director interview on September 24, 2020 at 11:20 AM, it was determined that the POL failed to establish and follow a Quality Assessment Program to monitor the following requirements of the analytic system: test procedures, reliable instruments, reliable reagents, control procedure and quality control records since January 2019. The annual volumes records showed that the POL examined and reported 200 Mohs cases during January 2019. The findings include: 1. The POL did not have a Quality Assessment Program to monitor the following requirements of the analytic systems: test procedures, reliable instruments, reliable reagents, control procedure and quality control records since January 2019. 2. The annual volumes records showed that the POL examined and reported 200 Mohs cases during January 2019. 3. The POL director confirmed on September 24, 2020 at 11:20 AM, that the POL did not have available a Quality Assessment Program to monitor the analytic system since January 2019.
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 lack of Quality Assessment Program, lack of quality assessment records and physician office laboratory (POL) director interview on September 24, 2020 at 11:20

	AM, it was determined that the POL failed to establish and follow a Quality Assessment Program to monitor the following requirements of the postanalytic system: turn around time and completeness of the patient's final test reports since January 2019. The annual volumes records showed that the POL examined and reported 200 Mohs cases during January 2019. The findings include: 1. The POL did not have a Quality Assessment Program to monitor the postanalytic system: turn around time and completeness of the patient's final test reports since January 2019. 2. The annual volumes records showed that the POL examined and reported 200 Mohs cases during January 2019. 3. The POL director confirmed on September 24, 2020 at 11:20 AM, that the POL did not have available a Quality Assessment Program to evaluate the postanalytic system since January 2019.
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 lack of Quality Assessment Program, lack of quality assessment records and physician office laboratory (POL) director interview on September 24, 2020 at 11:20 AM, it was determined that the POL director failed to ensure compliance with quality assessment (QA) requirements since January 2019. The findings include: 1. The POL director failed to establish a Quality Assurance Program to assess the general laboratory systems requirement. Refer to D 5291. 2. The POL director failed to establish a Quality Assurance Program to assess to the preanalytic systems requirements. Refer to D 5391. 3. The POL director failed to establish a Quality Assurance Program to assess the analytic systems requirements. Refer to D 5791. 4. The POL director failed to establish a Quality Assurance Program to assess the postanalytic systems requirements. Refer to D 5891. 5. The POL director confirmed on September 24, 2020 at 11:20 AM, that the Quality Assessment Program was not available since January 2019.