Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0998625	01/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermasurgery	Bayamon Medical Plaza Suite 907, Bayamon, 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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on quality control records review and interview with the laboratory director and laboratory personnel on January 18, 2019, it was determined that the laboratory failed to ensure compliance with the analytic system requirements of Mohs Micrographic surgery. Refer to D5311, D5411 and D5601.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of slides labeling written instructions, laboratory personnel and director interview and observation of slides, it was determined that the laboratory did not follow the written instructions for patient slides labeling. The findings includes: a. The written instructions for slides labeling were reviewed on January 18, 2019 at 11: 05 am. b. The written instructions stated that all slide must be labeled with an

	accession number, patient name and number of slides. c. Slides reviewed at random showed that the slides were labeled with the accession number, but and additional number was included. d. The laboratory personnel stated that besides the accession number he included the year in which the case was performed. However the written instructions did not include any reference to the year. e. Review of 5 slide boxes with cases from the week of January 15, 2019 showed that all of them (73 slides) were labeled only with the patient name. f. The laboratory personnel stated that he did not include the accession number until the case was closed and the final report printed. g. The laboratory director stated on January 18, 2019 at 11:10 am that the instructions were not followed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: 1. Based on review of the cryostat preventive maintenance log and interview with the laboratory personnel on January 18, 2019 at 10:15 am, it was determined that the laboratory did not perform ,the every 6 to 8 week maintenance, since October 2018. The findings include: a. The cryostat preventive maintenance log was review from January 2017 to January 2019. The maintenance log showed that the every 6 to 8 week preventive maintenance was not performed since October 2018. b. The laboratory personnel stated that the preventive maintenance was not performed since October 2018. ac. A total of 231 patient's cases were performed since October 2018. 2. Based on review of the sterilizer preventive maintenance log and interview with the laboratory personnel on January 18, 2019 at 10:20 am, it was determined that the laboratory did not perform the monthly preventive maintenance since October 2018. The findings include: a. The sterilizer preventive maintenance log was review from January 2017 to January 2019. The maintenance log showed that the monthly was not performed since October 2018. b. The laboratory personnel stated that the preventive maintenance was not performed since October 2018.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of quality control records , stain evaluation record log and interview with the laboratory personnel on January 18, 2019 at 10:22 am, it was determined that the laboratory did not include a control slide of known reactivity with each patient slide or group of slides. The findings includes: a. The laboratory used the Toluidine

	Blue Stain for Mohs Micrographic surgery. b. The laboratory personnel state, that each six months the laboratory evaluates 5 patient's slides for neatness, poor staining , incomplete sections and artifacts. They used this evaluation as quality control. c. The stain evaluation record log (years 2017 to 2019) was reviewed , showing the each six months 5 slides evaluations
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 quality control, preventive maintenance records and patient slides review on January 18, 2019, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the Mohs Micrographic surgery 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 review of records and interview with the laboratory director on January 18, 2019, it was determined that the laboratory director did not fulfill his responsibilities with the Mohs Micrographic surgery quality control procedures. The finding includes: a. The laboratory director director did not assure that preventive maintenance were followed, did not include an known control slide nor assure that the written instructions for slide labeling were followed. Refer to D 5311, D 5411 and D 5601.