Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2146676	11/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Jane Yoo Md Pllc	162 West 56th Street, Suite 304-305, New York, NY	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual an and interview with the laboratory director, It was confirmed with the laboratory director on November 6, 2018 at approximately 10:45 am that the director failed to approve, sign and date the laboratory procedure manual.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a lack of records, surveyor's observation, and an interview with the laboratory director, the laboratory began patient specimen testing for Moh's surgery in July 2018 and failed to validate the cryostat. Findings Include: It was confirmed with

	the laboratory director on November 6, 2018 at approximately 10:45 am that the laboratory failed to validate the Leica cryostat instrument prior to start of patient testing.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure manuals and an interview with the laboratory director, the laboratory director failed to approve (sign and date) the laboratory's manual for Moh's Surgery. Refer to: D5407
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 a review of records, surveyor's observation, and an interview and confirmed by the Moh's processor on November 6, 2018 at approximately 10:45 AM, the laboratory director failed to ensure that the QA program for histology testing was maintained to ensure quality laboratory services. Refer to: D5421