Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0691460	01/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Peter A Klein, Md Faad, Pc	100 Hospital Road, Suite 116, Patchogue, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a lack of humidity records an and interview with the Practice manager and the laboratory director, the laboratory failed to follow the manufacturer's instructions to monitor and document the room humidity where Mohs testing is performed. Findings Include: It was confirmed by the practice manager and the laboratory director, on January 17, 2019, at approximately 11:00 AM that the laboratory failed to follow the manufacturer's written criteria to monitor and document the humidity of the room where Mohs testing is performed from April 2017 through the date of this survey.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on reviewing randomly selected pathology test reports and confirmation by the laboratory director/pathologist, the laboratory failed to indicate on the pathology reports the address of the laboratory where the professional component of the dermatopathology is performed. Findings include: On January 17, 2019 at approximately 11:00 AM, the laboratory director/pathologist confirmed surveyor's findings that although the laboratory moved to a new location in June 2018, the pathology reports still indicate the previous laboratory's address. PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON APRIL 4, 2017.
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 surveyor review of the quality assessment (QA) program and confirmed in an interview with the laboratory director and the practice manager at the time of the survey, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to: D5413, D5805