Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0986904	02/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
David E Bank Md Pc Dba The Center For Dermatology	359 East Main Street Suite 4g, Mount Kisco, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a lack of the verification records and an interview with the Moh's processor, the laboratory failed to verify the accuracy of the Moh's surgery slides at least twice per year. Finding Includes: The Moh's processor confirmed on February 20, 2019, at approximately 10:10 AM that twice annual verification was not performed for Moh's surgery slides in 2018. Approximately 96 patient slides were read and results reported for Moh's surgery.
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 and an interview with the Moh's processor, the laboratory failed to follow the manufacturer's instructions to monitor and document

	the humidity. Findings Include: The Moh's processor confirmed on February 20, 2019, at approximately 10:10 AM that the laboratory failed to follow the manufacturer's directions to monitor and document the humidity of the room where Moh's processing occurs from June 2017 through the date of this survey.
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 surveyor review of maintenance records and an interview with the Moh's processor, the laboratory failed to follow the manufacturer's requirements for instrument maintenance. Findings include: The Moh's processor confirmed on February 20, 2019, at approximately 10:15 AM that the laboratory failed to perform yearly maintenance for the cryostat and fumehood used to process patient tissue for Moh's surgery. Maintenance for both instruments was last performed in 2016. Approximately 96 patient specimens were processed during that time.
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 procedures and an interview with the Moh's processor, 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 D5217, D5413 and D5429