Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2076613	02/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Scott Sanders Md Pllc	301 North Main Street, Suite 3, New City, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on a lack of procedures, surveyor observation and an interview with the Moh's processor, the laboratory failed to establish and have accessible a safety procedure to protect the laboratory staff from physical, chemical, biochemical, biohazard material and electrical hazards. Findings Include: It was confirmed with Moh's processor on February 12, 2018 at approximately 11:45 am that the medical assistants cups and glasses were in the laboratory where fungal culture and KOH slides are prepared and read.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's observation of the reagents used for mycology and an interview with the MOH's processor, the laboratory failed to discontinue the use of expired mycology reagents. FINDINGS: It was confirmed with the Moh,s processor on February 12, 2018 at approximately 11:45 AM that the KOH reagents in use in the laboratory had expired on March 14, 2016 - Lot# 15169. Approximately 276 patient

	specimens were tested and results released from February 10, 2016 through the date of this survey.
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 and an interview with the Moh's processor, the laboratory obtained and began testing on the new Leica cryostat instrument in September 2016 and failed to validate the instrument prior to patient testing.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of quality control (QC) records for dermatophyte media (DTM) used to perform fungal testing and an interview with the Moh's processor, the laboratory failed to perform the sterility check on DTM. Findings Include: It was confirmed with the Moh's tech on February 12, 2018, at approximately 12:00 PM, that the sterility check for each new batch (shipment) or lot number of DTM in use was not performed from March 31, 2016, through the date of the survey. Approximately 276 patients tests were performed and read during that time period. This is a repeat citation from the surveys of October 21, 2014, and March 31, 2016.
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 the surveyor findings and confirmed in an interview with the Moh's processor, the laboratory director failed to provide overall management of the

	laboratory. The laboratory director failed to ensure that the: 1. Plan of correction from the survey conducted on March 31, 2016 was implemented and maintained. 2. Laboratory's QC program for fungal cultures were maintained. Refer to D6093. 3. Laboratory's Quality Assurance (QA) program for mycology was maintained. Refer to D6084 and D6094. This is a repeat citation from the survey of March 31, 2016.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation and confirmed in an interview with the Moh's processor, the director must provide a safe environment in which employees are protected from physical, chemical and biological hazards. Refer to D3011
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 a review of QC records, and confirmed in an interview with the Moh's processor, the laboratory director failed to ensure that the QC program for mycology was followed to assure the quality of laboratory services. Refer to D5477
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, surveys observation and an interview with the laboratory director on February 12, 2018 at approximately 11:35 AM, the laboratory director failed to ensure that the QA program for histology pathology testing was maintained to ensure quality laboratory services. Refer to: D5417, and D5421 This is a repeat citation from the surveys of October 21, 2014, and March 31, 2016.