Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0371496	08/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Georgetown Dermatologists Pc	39242 Dequindre Ste 105, Sterling Heights, MI	

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
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The laboratory director failed to provide overall management and direction for 2 (August 2017 to August 2019) of 2 years. Findings include: 1. The laboratory director failed to establish an acceptable Individualized Quality Control Plan (IQCP) to assure the quality of fungal cultures. Refer to D6020.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory director failed to establish an acceptable Individualized Quality Control Plan (IQCP) to assure the quality of fungal cultures for 2 (August 2017 to August 2019) of 2 years. Findings include: 1. A record review of the laboratory's established Individualized Quality Control Program (IQCP) showed lack of laboratory director review and

	approval. 2. . A review of the laboratory's IQCP revealed a section titled "Risk Assessment" and did not contain the following components: a. The identification and evaluation of potential failures and sources of errors in the testing process and the frequency and impact of those failures and sources of error on test quality. b. Documentation of all activities completed for the risk assessment decisions. c. Data to support the laboratory's risk assessment decisions including in-house data, established by the laboratory in its own environment and by its own personnel demonstrating the stability of the test system as it is used in the laboratory supports the number and frequency of the quality control documented in the quality control plan. 3. A review of the laboratory's IQCP revealed a section titled "QCP" and did not contain a description of the practices, resources, and procedures to control the quality of the fungal culture test process. The quality control plan did not contain the number, type, frequency of testing and criteria for acceptable result(s) of the quality control. 4. A review of the laboratory's IQCP revealed a section titled "QA" and did not contain procedures for the ongoing monitoring of the effectiveness of their IQCP. 5. An interview on 8/13/19 at 10:45 am with the office manager confirmed the IQCP was in use by the laboratory.