Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0685509	02/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dermatologists Of Southwest Ohio	100 W Third Avenue, Suite 250, Columbus, OH	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Manager, the laboratory failed to include in the their policies and procedures the KOH (potassium hydroxide) and scabies requirements for specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. Seven out of seven patients tested from 02/26

	/2020 through 10/30/20 had the potential to be affected by this deficient practice. Findings Include: 1. A virtual review of the laboratory's policies and procedures on 02 /24/2021 failed to find policies and/or procedures for the KOH and scabies tests. 2. A virtual review of patient records and reports found seven patients tested for either KOH or scabies. Patient Test Date 1 KOH 02/26/20 2 Scabies 03/03/20 3 KOH 05/12 /20 4 KOH 06/16/20 5 KOH 06/26/20 6 KOH 09/23/20 7 KOH 10/30/20 3. An email interview with the Practice Manager, on 02/26/20, confirmed that the laboratory had policies and procedures for KOH and scabies, but were unable to locate them; thus, the lab failed to produce policies and procedures for KOH and scabies at the time of inspection.