Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0687229	06/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of West Michigan	1740 E Paris Avenue Se, Grand Rapids, 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
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 record review and interview, the laboratory failed to perform and document the room temperature and humidity readings for the mycology, parasitology, virology, dermatopathology, and Mohs' instrumentation in use for two (May 2016 to May 2018) of two years of operation. Findings include: 1. On June 20, 2018 record review revealed the laboratory did not perform and document room temperature and humidity readings for the microscopes, the dermatopathology tissue processing instrumentation, and the microscopic examination of the processed tissue slides for two (May 2016 to May 2018) of two years as follows: a. mycology, parasitology, and virology microscope examination 1. garden level - two microscopes 2. central level - five microscopes b. dermatopathology tissue processing instruments and microscope c. Mohs' tissue processing instruments and microscope 2. During the interview on June 20, 2018 at approximately 2:50 PM, the office manager confirmed the room temperature and humidity readings were not performed and documented in the laboratories.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system

	performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on observation, lack of records, and interview, the laboratory failed to establish, perform, and document thermometer calibrations for two (May 2016 to May 2018) of two years to ensure proper operation of the GE refrigerator that stored the Periodic Schiff stain. Findings include: 1. On June 20, 2018 at 11:30 AM during a tour of the laboratory, the surveyor observed a GE refrigerator used to store the Periodic Schiff stain with a min/max thermometer in use with a sticker on the back side labeled with "RC 10/2015". 2. On June 20, 2018 at 11:40 AM, lack of records revealed the laboratory did not establish, perform, and document thermometer calibrations for two (May 2017 to May 2018) of two years of operation. 3. During the interview on June 20, 2018 at 2:50 PM, testing personnel #7 as listed on the CMS-209 confirmed the laboratory did not establish, perform, and document thermometer calibrations for the min/max thermometer.