

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0879485	(X3) Date Survey Completed 03/08/2018
Name of Provider or Supplier Hamzavi Dermatology	Street Address, City, State 2950 Keewahdin Road, Fort Gratiot, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview, the laboratory failed to follow the manufacturer's operator's manual to monitor and record the humidity readings in the laboratory for 22 of 22 months reviewed to ensure reliable Leica CM 1510S cryostat operation. Findings include: 1. On March 8, 2018 at 10:34 a.m., document review of the maintenance log for the room temperature revealed there was no monitoring and documenting of the humidity for 22 (April to December 2016, 2017, and January to February 2018) of 22 months reviewed in 2016, 2017, and 2018. 2. During the interview on March 8, 2018 at 10:34 a.m., one of the Mohs' processing techs confirmed the humidity readings were not monitored and documented each day of patient testing.</p>