Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0694147	(X3) Date Survey Completed 05/09/2019
Name of Provider or Supplier Psoriasis And Eczema Treatment Center	**Street Address, City, State** 597 Baldwin St, Jenison, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with a staff member, the laboratory failed to monitor and document the room temperature and humidity in the microscope room for 2 (May 2017 to May 2019) of 2 years. Findings include: 1. A review of the Optech Microscope Operator's Manual revealed the environment temperature range for operation is between 5 and 40 degrees C and the relative humidity range is less than 80%. 2. An interview with a staff member on 5/9/19 at 9:39 am confirmed room temperature and humidity readings had not been performed and documented for the microscope room.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on patient chart audit and an interview with a staff member, the laboratory failed to document the date reported on 2 (#1 and #2) of 23 test reports reviewed. Findings include: 1. A chart audit of 23 patients revealed 2 patients were missing the date the tests were reported on the final report. 2. An interview with a staff member on 5/9/19 at 11:30 am confirmed the dates were absent.