Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1015730	10/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Livonia Dermatology	14801 Farmington Road, Livonia, 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
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director and Testing Personnel #2, the laboratory failed to document the time it receives a specimen for 4 (patients #7, #8, #11, and #12) of 12 patient charts reviewed. Findings include: 1. A review of 12 patient charts revealed the following patients had MOHS specimens collected without documentation of the time received by the laboratory for the following patients: a. Patient #7, surgery performed 8/28/19 b. Patient #8, surgery performed 3/14/19 c. Patient #11, surgery performed 4/5/18 d. Patient #12, surgery performed 11/9/17 2. An interview on 10/1/19 at 12:29 pm with the Laboratory Director and Testing Personnel #2 confirmed the above patient specimens did not have the time received by the laboratory documented.
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 observation, record review, and interview with Testing Personnel #2, the laboratory failed to monitor humidity for 2 (October 2017 to October 2019) of 2 years. Findings include: 1. An observation on 10/1/19 at 10:05 am by the surveyor revealed the laboratory did not have a humidity monitor. 2. A record review of the Leica Cryostat CM 1850 Operator's Manual revealed a section titled "Site Requirements" stating, "Air humidity must not exceed 60%." 3. An interview on 10/1 /19 at 10:05 am with Testing Personnel #2 confirmed the laboratory was not monitoring humidity.
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: A. Based on record review and interview with the Laboratory Director and Testing Personnel #2, the laboratory failed to provide positive patient identification for 1 (patient #7) of 12 patient charts reviewed. Findings include: 1. A review of 12 patient charts revealed patient #7 had MOHS surgery performed on 8/28/19. 2. A review of the MOHS map from patient #7 dated 8/28/19 revealed a lack of two patient identifiers. 3. An interview on 10/1/19 at 12:30 pm with the Laboratory Director and Testing Personnel #2 confirmed patient #7 did not have two patient identifiers on the MOHS map. B. Based on record review and interview with the Laboratory Director and Testing Personnel #2, the laboratory failed to indicate the name and address of the laboratory location where testing was performed for 2 (October 2017 to October 2019) of 2 years. Findings include: 1. A review of patient charts revealed MOHS maps without the name and address of the laboratory performing testing. 2. An interview on 10/1/19 at 12:30 pm with the Laboratory Director and Testing Personnel #2 confirmed the name and address were not on the MOHS map in use by the laboratory.