Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2274436	11/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Zarka Dermatology	1057 Suncrest Drive, Lapeer, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on record review, observation, and interview with the Mohs Technician, the laboratory failed to ensure staff protection from chemically hazardous materials for 10 (January 2023 to November 2023) of 10 months since the laboratory started performing histopathology testing. Findings include: 1. A review of the laboratory's "Safety Data Sheet" for its Reagent Alcohol 100% revealed a section stating, "Eye Contact. Immediately flush with plenty of water for at least 15 minutes separating eyelids occasionally." 2. An observation of the laboratory on 11/15/23 at 9:35 am revealed a lack of eye wash station. 3. An interview on 11/15/23 at 9:35 am with the Mohs Technician confirmed the laboratory did not have an eye wash to use.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to establish policies and procedures to assess testing personnel, clinical consultant, technical supervisor, and general supervisor competency for 10 (January

	2023 to November 2023) of 10 months since the laboratory started histopathology testing. Findings include: 1. A review of the laboratory's procedures revealed a lack of process to assess testing personnel, clinical consultant, technical supervisor, and general supervisor competency. 2. An interview on 11/15/23 at 10:24 am with the Laboratory Director confirmed the laboratory had not established policies and procedures to assess testing personnel, clinical consultant, technical supervisor, and general supervisor competency.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to document time of histopathology specimen receipt into the laboratory for 3 (Patients 1, 7, and 10) of 11 patient test records reviewed. Findings include: 1. A review of the laboratory's patient test records revealed a lack of documented time of specimen receipt into the laboratory for the following patients: a. Patient #1 had testing performed on 1/18/23. b. Patient #7 had testing performed on 7/10/23 for four stages of mohs surgery and no documentation of specimen receipt into the laboratory for the four specimens. c. Patient #11 had testing performed on 10/11/23 on two stages of mohs surgery and no documentation of specimen receipt into the laboratory for the second specimen. 2. An interview on 11/15/23 at 11:22 am with the Laboratory Director confirmed the patients listed above did not have the time of specimen receipt into the laboratory documented.