Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2021984	07/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Clarkston Dermatology	5701 Bow Pointe Drive Suite 215, Clarkston, 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 with a Medical Assistant (MA), the laboratory failed to perform and document the refrigerator every 3 months maintenance for 1 (April 2023) of 6 checks from January 2022 to July 25, 2023. Findings include: 1. A review of the "Equipment Quality Control Refrigerator Maintenance Record" revealed the following tasks to be performed and documented every 3 months for the refrigerator: a. check door gasket seal b. defrost/clean. c. grounding 2. Record review of the "Equipment Quality Control Refrigerator Maintenance Record" log revealed a lack of documentation for the 3 months maintenance for 1 (April 2023) of 6 checks reviewed. 3. An interview on 7/25/2023 at 11:58 am, a MA confirmed the laboratory failed to perform and document the April 2023 refrigerator maintenance.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with Medical

	Assistant (MA), the laboratory failed to perform and document the quarterly patient chart review for the histopathology/Mohs' testing for 2 (March and June 2023) of 6 quarterly checks in 2022 and 2023. Findings include: 1. Record review of the "Quality Assurance Audit - Patient Chart Review" logs revealed no documentation for 2 (March and June 2023) of 6 quarterly checks in 2022 and 2023. 2. When queried on 7 /25/2023 at 12:05 pm, a MA was unable to provide the surveyor documentation to show the quarterly checks had been performed. 3. An interview on 7/25/2023 at 12:03 pm, a MA confirmed the quarterly patient chart reviews had not been performed for March and June in 2023.