Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2021984	11/04/2019
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with the back staff manager (BSM), the laboratory failed to retain 3 (D1241-0817, D1288-0818, and D1312-0219) of 3 manufacturer's package insert for 2 years. Findings include: 1. Record review revealed the laboratory was using "ACU-DTM" Dermatophyte Test Medium (DTM), selective medium for the detection of dermatophytes. 2. Record review of the package inserts revealed the laboratory did not retain 3 of 3 manufacturer's package insert for 2 years as follows: a. D1241-0817 b. D1288-0818 c. D1312-0219 3. During the interview on 11/4/2019 at 10:45 am., the BSM acknowledged the manufacturer's package inserts were not retained for 2 years.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on record review and interview with the back staff manager (BSM), the laboratory failed to perform verification of accuracy for the potassium hydroxide (KOH) and dermatophyte test medium (DTM) testing for 2 (November 2017 to November 2019) of 2 years. Findings include: 1. A record review revealed a lack of

	documentation for the twice annual verification of accuracy for the KOH and DTM testing for 2 of 2 years. 2. During the interview on 11/4/2019 at 11:30 am, the BSM acknowledged the verification of accuracy for the KOH and DTM testing was not performed and documented.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the back staff manager (BSM), the laboratory failed to perform and document media checks for the "ACU-DTM Dermatophyte Test Medium (DTM)" with each new batch, lot, or shipment for sterility, physical characteristics, and the ability to support growth of yeast for 2 (November 2017 to November 2019) of 2 years. Findings include: 1. A record review of "ACU-DTM (Dermatophyte Test Medium) Directions for Use" in the package insert exposed a section stating, "CLIA requires the end user to perform a minimum of a positive and negative control on each new lot or batch purchased." The table indicated the microorganisms to use for quality control were, "Trichophyton mentagrophyte, E. coli, and Candida albicans." 2. A record review of the DTM section of the "KOH & DTM Log" book revealed a lack of documentation for the media checks for sterility, physical characteristics, and a control for the yeast (Candida albicans) for 2 of 2 years. 3. When requested by the surveyor on 11/4/2019 at approximately 10:35 am, the BSM was not able to provide records of performing the sterility, physical characteristics, and the yeast control on the DTM. 4. During the interview on 11/4/2019 at approximately 10:35 am., the BSM acknowledged the media checks for sterility, physical characteristics and the ability to support growth of yeast had not been performed.