Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2131927	(X3) Date Survey Completed 02/26/2020
Name of Provider or Supplier Singer Dermatology	**Street Address, City, State** 29355 Northwestern Highway Suite 302 B, Southfield, 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
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 office manager, the laboratory failed to assess employee and consultant competency for 2 (Testing Personnel #1 (TP1) and Testing Personnel #2 (TP2)) of 6 personnel listed on the CMS 209 form. Findings include: 1. A review of the laboratory's competency records revealed a lack of competency records in 2019 for the following employees: a. TP1, also functioning as Clinical Consultant #1, the Technical Consultant, Technical Supervisor #1, and General Supervisor #1. b. TP2, also functioning as Clinical Consultant #2, Technical Supervisor #2, and General Supervisor #2. 2. An interview on 2/26/2020 at 9:26 am with the office manager confirmed competency assessments were not performed on the two laboratory employees listed above.
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 office manager, the laboratory failed to verify the accuracy of fungal culture testing for 2 (February 2018 to February 2020)

	of 2 years reviewed. Findings include: 1. The surveyor requested twice annual verification of accuracy documentation for fungal culture testing on 2/26/2020 at 10: 32 am and it was not made available. 2. An interview on 2/26/2020 at 10:32 am with the office manager confirmed the laboratory did not perform verification of accuracy on fungal culture testing.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (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 office manager, the laboratory failed to check each shipment of fungal culture media for positive and negative reactivity for 2 (February 2018 to February 2020) of 2 years reviewed. Findings include: 1. A record review of the laboratory's "Mycosel Received Log" and "Mycosel Controls" log revealed shipments of mycobiotic agar received on the following dates were not checked for positive and negative reactivity: a. Lot number 1805210 received on 3/21 /18 b. Lot number 1805210 received on 6/13/18 c. Lot number 1805210 received on 7 /11/18 d. Lot number 1805210 received on 7/25/18 e. Lot number 1805210 received on 8/15/18 f. Lot number 1805210 received on 9/5/18 g. Lot number 1805210 received on 9/19/18 h. Lot number 1805210 received on 10/3/18 i. Lot number 1805210 received on 11/14/18 j. Lot number 1805210 received on 11/28/18 k. Lot number 1834608 received on 1/29/19 l. Lot number 1834608 received on 2/7/19 m. Lot number 1834608 received on 2/20/19 n. Lot number 1834608 received on 3/6/19 o. Lot number 1904506 received on 5/17/19 p. Lot number 1904506 received on 6/17 /19 q. Lot number 1904506 received on 6/29/19 r. Lot number 1904506 received on 7 /12/19 s. Lot number 1904506 received on 7/25/19 t. Lot number 1904506 received on 8/14/19 u. Lot number 1904506 received on 8/21/19 v. Lot number 1904506 received on 8/23/19 w. Lot number 1904506 received on 9/10/19 x. Lot number 1904506 received on 9/19/19 y. Lot number 448215 received on 1/22/2020 2. An interview on 2/26/2020 at 11:00 am with the office manager confirmed each shipment of fungal culture media was not tested for positive and negative reactivity.