Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2131927	03/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Singer Dermatology	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 procedure manual review, record review, and interview, the laboratory failed to ensure written competency policies were established, contained the requirements from subpart M, and implemented for three (#4-#6) of five testing personnel performing the parasitology and mycology testing in 2017 and 2018. Findings include: 1. On March 26, 2018 at 11:30 a.m., procedure manual review revealed the laboratory did not establish a written competency policy that included the competency requirements from subpart M and for the mycology and parasitology testing that included the following: a. Direct observations of routine patient test performance, patient preparation, specimen handling, processing, and testing. b. Monitoring the recording and reporting of patient test results. c. Review of test results, worksheets, quality control records, proficiency testing results, and preventive maintenance. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of problem solving skills. 2. On March 26, 2018 at 11: 30 a.m., record review revealed the laboratory did not have any documentation to show that for three of five testing personnel the competency assessments were performed and documented for the mycology and parasitology testing. 3. On March 26, 2018 at 11:30 a.m. when queried, the office personnel was not able to provide the surveyor with a competency policy that contained the six minimal requirements and the documentation of those requirements for three of five testing personnel performing the mycology and parasitology testing from July 6, 2017 to March 26, 2018. 4. During the interview on March 26, 2018 at 11:30 a.m., the office personnel

	confirmed the laboratory did not establish a competency policy that contained the requirements from Subpart M and did not implement the policy.
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, the laboratory failed to perform and document media checks for the mycobiotic agar with each new batch, lot, or shipment of media for sterility, the ability to support growth, and selectivity/inhibition or biochemical responses for 12 (lot # 1706616, 1709414, 1709414, 1709414, 1718804, 1718804, 1718804, 1718804, 1731807, 1718804, 1805210, and 1805210) of 12 lots received in 2017 and 2018. Findings include: 1. On March 26, 2018 at 10:40 a.m., record review of the "Mycosel Received Log" for 12 of 12 mycobiotic agar "Certificate of Analysis" sheets revealed there was no documentation to show the sterility, the ability to support growth, and selectivity/inhibition or biochemical responses of the media for each new batch, lot or shipment was performed in 2017 and 2018. 2. During the interview on March 26, 2018 at 10:40 a.m., the office personnel confirmed the media checks were not performed and documented.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to document the corrective action taken for two (February 8 and March 8) of three temperatures recorded for the operation of the Leica CM 1510S cryostat during tissue processing in 2018. Findings include: 1. On March 26, 2018 at 11:46 a.m., record review of the "Temperature Monitor Log for Refrigerators, Freezers, Cryostats" revealed for two of three days of operation the temperatures documented were not within the stated range of -20 to -30 degrees C as follows: a. February 8, 2018 - [-19] degree C b. March 8, 2018 - [-18] degree C 2. On March 26, 2018 at 11:46 a.m. when queried, the office personnel were not able to provide the surveyor documentation to show corrective

	action was taken for the temperatures outside the operational range. 3. During the interview on March 26, 2018 at 11:46 a.m., the office personnel confirmed no corrective action was taken for the temperatures outside the operational range.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to establish a system to ensure the manually transcribed results for one (#12) of 16 patient charts audited were accurately reported from point of entry to the final report. Findings include: 1. On March 26, 2018 at 12:26 p.m., record review for one of 16 patient charts audited revealed the mycology potassium hydroxide test was inaccurately entered into the patient's electronic medical record. 2. During the interview on March 26, 2018 at 12: 26 p.m., an office personnel confirmed the manually entered results were not transcribed accurately.