Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0871376	03/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Skin & Vein Center Of Sterling Heights	44056 Mound Suite 101, Sterling Heights, 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 review, record review, and interview with testing personnel #5 (TP5), the laboratory failed to ensure competency policies were followed for one (#2) of five TP performing the mycology and parasitology testing. Findings include: 1. Procedure review of the "CLIA Statement Book" under the "Personnel Review Information" section revealed the competency is to assessed every six months. 2. Record review of the TP competency assessments revealed their was no documentation to show the 2nd six month of 2017 and the 2018 assessments were performed and documented for TP2. 3. During the interview on March 14, 2019 at 2: 08 PM, TP5 acknowledged the competency policy had not been followed for TP2 in 2017 and 2018.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #5 (TP5), the

	laboratory failed to perform and document the refrigerator and dermatophyte testing media (DTM) incubation drawer temperature for 37 (November 7-30 and December 3-31) of 41 days of operation in 2018 for the storage and incubation of the DTM media. Findings include: 1. Record review of the "Daily DTM Temperature" log for the incubation drawer and the "Daily DTM Temperature" log for the refrigerator showed the laboratory did not document the temperatures for 37 days of operation in 2018 as follows: a. November 7-9, 12-16, 19-21, 23, and 26-30 b. December 3-7, 10-14, 17 - 21, 24, 26-28, and 31. 2. During the interview on March 14, 2019 at approximately 12: 38 PM, TP5 confirmed no temperatures were taken and recorded prior to testing patients.
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 with testing personnel #5 (TP5), the laboratory failed to document the corrective action taken for temperatures outside the stated range for three (January - March 2019) of 24 months reviewed. Findings include: 1. Record review of the "Daily DTM Temperature" logs for the dermatophyte testing media (DTM) incubation drawer revealed the temperature was below the stated range of 22-30 degree C (72 - 86 degree F) and no corrective action was documented as follows: a. January 2019 - 2-4, 7-8, 10-11, 14-18, 21-25, and 28-31 b. February 2019 - 1, 6-8, 13-15, 18-22, 27-28 c. March 2019 - 8 and 11 2. During the interview on March 14, 2019 at approximately 12:38 PM, TP5 acknowledged the laboratory did not document corrective action for the temperatures outside the stated 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 with testing personnel #5 (TP5), the

	laboratory failed to establish a system to ensure the manually recorded patient test results in the patient's chart correlates with the electronic specimen log for one (medical record number 3324870/ #20) of 22 patient charts audited. Findings include: 1. Record review of the patient's chart compared to the electronic specimen log revealed the results did not correlate as follows: a. patient's chart for fungal culture result - negative b. electronic specimen log for fungal culture result - positive 2. During the interview on March 14, 2019 at approximately 2:30 PM, TP5 acknowledged that a discrepancy exists between the patient's chart and the electronic specimen log.