Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0687229	06/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of West Michigan	1740 E Paris Avenue Se, Grand Rapids, 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 Testing Personnel #16 (TP16), the laboratory failed to ensure a written policy was established and implemented that included the competency requirements from subpart M for the mycology, parasitology, and virology testing for 7 (TP9 to TP14, and TP18) of 15 testing personnel for the past 15 months reviewed. Findings include: 1. Record review revealed the laboratory did not establish and implement a competency assessment that contained the following six minimum regulatory requirements as follows: 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 test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and f. Assessment of problem solving skills. 2. Record review revealed a lack of documentation of TP competency assessments for 7 (TP9 to TP14 and TP18) of 15 testing personnel performing mycology potassium hydroxide (KOH), parasitology scabies, and virology Tzanck smears for 15 months of testing. 3. An interview on 6/21/2022 at 12:02 pm, TP16 confirmed no policy had been established or implemented. .
D5301	TEST REQUEST CFR(s): 493.1241(a)

	The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #16 (TP16), the laboratory failed to have a documented request for patient testing from an authorized person for 1 (#5) of 8 patient charts reviewed. Findings include: 1. A record review of the "KOH/Tzanck/Scabies Log" patient testing logs revealed for 1 (#5) of 8 patient charts reviewed there was no order in the patients electronic medical record (EMR) for the potassium hydroxide (KOH) performed on 5/25/2021. 2. An interview on 6/21 /2022 at 2:00 pm, TP16 confirmed their was no order in the EMR for patient #5 for KOH testing performed on 5/25/2022.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on observation and interview with Testing Personnel #16 (TP16), the laboratory failed to calibrate and/or replace the expired thermometer in the GE refrigerator for 15 (March 2021 to June 2022) of 15 months of operation. Findings include: 1. During a tour of the laboratory on 6/21/2022 at 9:10 am, the surveyor observed a traceable min/max thermometer in the GE refrigerator had expired on 6/23 /2020. 2. When queried on 6/21/2022 at 9:10 am, TP16 was not aware the thermometer had expired. 3. An interview on 6/21/2022 at 9:10 am, TP16 confirmed the thermometer had expired and was not calibrated and/or replaced.
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 document review and interview with Testing Personnel #16 (TP16), the laboratory failed to establish a system to 1) ensure the transcribed Mohs' surgery site

	was accurately reported for 1 (G3123-21) of 11 Mohs' cases reviewed and 2) ensure the Mohs' case number is accurately transcribed throughout the Mohs' survey process for 1 (A-1155-21) of 11 Mohs' cases reviewed. Findings include: 1. Record review revealed for 2 of 11 Mohs' cases reviewed, the surgical site on the pre-op biopsy report, the Mohs' map, Mohs' log, and the final report in the electronic medical record (EMR) system are not consistent and the Mohs' case number was not transcribed properly throughout the Mohs' survey process as follows: Mohs' a. G-3123-21 performed on 7/21/2021 i. Pre-op biopsy report and the EMR report - right lower cutaneous lip ii. Mohs' map and Mohs' log - right lower lip b. A-1155-21 performed on 9/22/2021 i. Case number on the Mohs' log - A-1155-21 ii. Case number on the slides and the EMR report - A-1151-21 2. An interview on 6/21/2022 at 12:54 pm, TP16 confirmed the locations on the pre-op biopsy report, Mohs' map, Mohs' log, and the final EMR report were not consistent with the original biopsy site and the Mohs' case number was not transcribed properly throughout the survey process.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #16 (TP16), the laboratory failed to include the results of testing performed for 1 (Patient #5) of 8 patient test reports reviewed . Findings include: 1. A review of patient test reports revealed for 1 (Patient #5) of 8 patient charts reviewed, the final test report for the potassium hydroxide (KOH) testing was not in the patient's electronic medical record (EMR). 2. When queried on 6/21/2022 at 12:00 pm, TP16 was unable to provide the surveyor test results in the EMR system. 3. An interview on 6/21/2022 at 12:00 pm, TP16 confirmed the testing was performed and documented on the "KOH/Tzanck /Scabies Log" sheet and not entered into the patient's EMR. ***Repeat Deficiency from 4/14/2016 survey***