Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0686342	09/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of Macomb - Oakland Pc	26850 Providence Parkway Ste 535, Novi, 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, the laboratory failed to ensure written competency policies were implemented for four (#5-#8) of eight testing personnel performing the moderately complex mycology and parasitology testing for two years. Findings include: 1. On September 12, 2018 at 12:30 PM, record review of the competency evaluations revealed for four (#5 - #8) of eight testing personnel the competency evaluations were not performed and documented for two (2017 and 2018) of two years as follows: a. testing personnel #5-#7 - no annual evaluation for 2017 and 2018 b. testing personnel #8 - no semi-annual evaluation for 2018 2. During the interview on September 12, 2018 at 12:30 PM, the office manager confirmed the competency evaluations were not performed and documented.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview, the laboratory failed to use the mycology potassium hydroxide 20% (KOH) reagent before the manufacturer's expiration date.

	Findings include: 1. During a tour of the laboratory on September 12, 2018 at 10:14 AM, the surveyor observed four of four bottles of KOH reagent in use with an expiration date of April 19, 2018 recorded on the manufacturer's label. 2. During the interview on September 12, 2018 at 10:14 AM, the office manager confirmed the KOH reagent was in use past the manufacturer's stated expiration date.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform and document the annual maintenance for 1) the mycology and parasitology microscope (Accu-Scope) and 2) the dermatopathology and Mohs' microscope (Olympus BH2) for one (2017) of three years of use. Findings include: 1. On September 12, 2018 at 10: 30 AM, record review of the preventive maintenance sticker on the two microscopes indicated the last preventive maintenance documented was October 17, 2016. When queried, the laboratory was unable to provide documentation to show the microscopes had been serviced in 2017. 2. During the interview on September 12, 2018 at 10:30 AM, the office manager confirmed the annual maintenance was not performed and documented in 2017.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on document review and interview, the processing laboratory failed to 1) provide documentation for the quality of the Hematoxylin & Eosinophil (H&E) stain and the professional interpretation of the tissue slide reading failed to 2) acknowledge and document the quality of the H&E stain for nine (#1 to #9) of nine patient charts audited. Findings include: 1. On September 12, 2018 at 12:15 PM, document review for nine of nine patient charts audited revealed the laboratory did not have documentation for 1) H&E stain quality from the processing laboratory and 2) the professional interpretation on the slide reading for the H&E stain quality. 2. On September 12, 2018 at 12:15 PM when queried, the office manager was not able to provide the surveyor documentation to show the processing laboratory and the professional interpretation of the H&E stain quality was performed and documented. 3. During the interview on September 12, 2018 at 12:15 PM, the office manager confirmed the H&E stain quality was not available from the processing laboratory and there was no documentation of the the stain quality during the interpretation of the slide reading.