Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0686342	08/01/2022
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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Office Manager, the laboratory failed to establish policies to ensure positive patient identification of specimens collected for 1 unlabeled Eswab specimen container observed. Findings include: 1. The surveyor observed a white Eswab specimen containter on the counter near the laboratory that did not have patient identifying information on 8/1/22 at 12:18 pm. 2. An interview on 8/1/22 at 12:18 pm with the Office Manager confirmed the specimen did not have patient identifying information on the specimen container. 3. An interview on 8/1/22 at 12:20 pm with the Laboratory Director revealed they collected the specimen and had left it on the counter without labeling it with patient identifying information before walking away. The specimen was to be sent out to a reference laboratory for bacterial culture. 4. A review of the laboratory's policies and procedures revealed a lack of policy regarding positive patient identification of patient specimens from the time of collection through the testing process or referral. 5. An interview on 8/1/22 at 1:45 pm with the Office Manager confirmed the laboratory had not established a policy for positive patient identification of patient specimens from the time of collection through the testing process or referral.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to establish a control procedure to assess and document positive and negative reactivity of immunohistochemical, differential, and special stain control slides for 16 (March 2021 to July 2022) of 16 months reviewed. Findings include: 1. A review of the laboratory's "Histopathology" procedure on 8/1/22 revealed a lack of an established process to assess and document positive and negative reactivity of immunohistochemical, differential, and specialt stain control slides. 2. A review of the laboratory's "Laboratory Quality Control Log- Professional Component Slides" logs from March 2021 to July 2022 revealed a lack of documented positive and negative reactivity of immunohistochemical, differential, and special stain control slides. 3. An interview on 8/1/22 at 2:38 pm with the Office Manager confirmed the laboratory had not established a procedure to assess and document positive and negative reactivity of immunohistochemical, differential, and special stain control slides.
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, record review, and interview with the Office Manager, the laboratory failed to ensure Potassium Hydroxide (KOH) reagent used in mycology testing had not exceeded its expiration date for 14 patients tested since the reagent had expired. Findings include: 1. The surveyor observed a bottle of EDM3 Solutions Potassium Hydroxide 10% in the laboratory with the expiration date of 3/23/22 on 8/1 /22 at 12:20 pm. 2. A review of the laboratory's "Potassium Hydroxide (KOH) examination" procedure revealed a section titled "Storage, Use and Handling" stating, "Do not use reagents after expiration date." 3. A review of the laboratory's "KOH and Scabies Log" patient testing log revealed a total of 14 patients had been tested with the expired KOH reagent since it had expired. 4. An interview on 8/1/22 at 12:20 pm with the Office Manager confirmed the KOH reagent had been expired and was used

	in patient testing after it exceeded its expiration date. ***This is a repeated deficiency from the 9/12/18 recertification survey***
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 record review and interview with the Office Manager, the laboratory failed to document the positive and negative reactivity of a known control slide for immunohistochemical, differential, or special stains for 16 (March 2021 to July 2022) of 16 months reviewed. Findings include: 1. An interview on 8/1/22 at 11:56 am with the Office Manager revealed the laboratory performs histopathology microscopic tissue examinations using specimens stained with immunohistochemical, differential, and special stains. 2. A review of the laboratory's "Laboratory Quality Control Log-Professional Component Slides" log on 8/1/22 revealed a column titled "Hematoxylin & Eosin (H&E) Differential Stain Quality Acceptable (Circle one)" and the laboratory had the option of circling "Y" for yes and "N" for no. The log did not include the control slide reactions for each special stain or immunohistochemical stain used. 3. An interview on 8/1/22 at 2:32 pm with the Office Manager confirmed the laboratory had not documented all control slide positive and negative reactions for immunohistochemical, differential, and special stains. ***This is a repeated deficiency from the 9/12/18 and 3/16/21 recertification surveys***