Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2022434	01/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Akron Dermatology, Inc	566 White Pond Drive Suite E, Akron, OH	

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
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 record review and an interview with the Histopathology processor (HP) #1, the laboratory failed to ensure that the histopathology stain, Eosin Y, was not used when it had exceeded its' expiration date. Findings Include: 1. Review of the laboratory's "Reagent Receipt Log", provided on the date of inspection, revealed Eosin Y Stain, lot number 1621043, was received on 09/06/2016, was opened on 08/21/2017, had expired on 08/03/2018, and was discarded on 09/20/2018 with the next lot number 1806819 of Eosin Y Stain opened on 09/20/2018. 2. HP#1 confirmed the Eosin Y Stain identified above was used for staining patient tissue biopsies beyond its' expiration date of 08/03/2018 through 09/20/2018. The interview occurred on 01/22/2019 at 3:20 PM.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on record review and interviews with the practice owner/operator and Histopathology processor (HP) #1, the laboratory failed to indicate the result of each Mohs test (stage/layer and piece) on the final test report. Findings Include: 1. Review of the laboratory's "Histopathology Mohs Laboratory" manual and the "Mohs Micrographic Surgery" policies and procedures, provided on the date of the inspection, did not find instructions to report Mohs results of tissue interpretation for each Mohs stage/layer and piece on the final test report. 2. Review of three out of nine of the laboratory's 2018 Mohs maps and test reports ("Visit Note") reviewed on the date of the inspection did not find a result for each Mohs test (piece of tissue per chuck) as indicated below: a) 4/23/18 Mohs Map - 5 layers, layer A/Stage 1 was bisected and frozen onto 2 chucks. The Mohs map indicated red markings identifying residual tumor in piece A1 and "+ Moderately differentiated SCC" was hand written on the Mohs Map. There were no red markings or a result for piece A2 indicated on the Mohs Map or in the Visit Note. Additionally, the letter sent to the referring physician did not indicate any test results for any layer/stage or piece. b) 8/27/18 Mohs Map - 3 layers, layer B/Stage 2 was bisected and frozen onto 2 chucks. The Mohs map indicated red markings identifying residual tumor in piece B2 and "+ Infiltrative BCC" was hand written on the Mohs Map. There were no red markings or a result for piece B1 indicated on the Mohs Map or in the Visit Note. Additionally, the letter sent to the referring physician did not indicate any test results for any layer/stage or piece. c) 12/31/18 Mohs Map - 2 layers, The letter sent to the referring physician did not indicate any test results for any layer/stage or piece. +; positive for residual tumor SCC; squamous cell carcinoma BCC; basal cell carcinoma 3. The laboratory owner/operator and HP#1 confirmed the Mohs test records and test reports did not indicate a test result for each test (layer/stage and piece) of tissue tested. The interviews occurred on 01/22/2019 at 3:35 PM.