Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2117712	04/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology & Skin Cancer Center	1039 Boardman-Canfield Road, Boardman, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director, Office Manager (OM) and Histopathology processor (HP), the laboratory failed to label the secondary containers of reagents, solutions and stains in the histopathology autostainer with the correct lot numbers and expiration dates. Findings Include: 1. Direct observation of the histopathology laboratory on 04/10/2018 at 1:27 PM, found the autostainer secondary containers were not directly labeled; there was a chart near the autostainer of the contents of each container and a reagent log for each of the reagents, solutions and stains and their lot numbers and expiration dates currently in use. 2. Further review of the reagent log and currently opened and in use hematoxylin stain revealed the reagent log indicated lot number 421288, expires 02/2019, but the currently opened and in use stock bottle of hematoxylin was lot number 436443, expires 06 /2019. 3. The HP confirmed the currently opened and in use hematoxylin stain was of a different lot number and expiration date as indicated on the reagent log and the laboratory personnel did not correctly document the information, as required. The interview occurred on 04/10/2018 at 1:27 PM.
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) If control materials are not available, the laboratory must have an alternative

	mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director, Office Manager (OM) and Histopathology processor (HP), the laboratory failed to have an alternative mechanism to detect immediate errors and monitor potassium hydroxide (KOH) and wet mount preparation testing performance when control material was not available. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any instructions for KOH and wet mount preparation QC testing procedures. 2. The Surveyor requested the laboratory's KOH and wet mount preparation QC policies and procedures and 2016, 2017 and 2018 KOH and wet mount preparation QC documentation from the Laboratory Director, OM and HP. The HP confirmed the laboratory did not establish a KOH and wet mount preparation QC policy and procedure, did not conduct and document any KOH and wet mount preparation QC activities every day of patient testing in 2016, 2017 and 2018, and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 04/10/2018 at 12:41 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 Laboratory Director, Office Manager (OM) and Histopathology processor (HP), 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 Mohs 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 three of the laboratory's 2017 and 2018 Mohs maps and test reports (Operative Notes) in which a stage/layer was cut/divided and each piece was frozen on individual chucks, did not find a result for each Mohs test (piece of tissue per chuck) as indicated below: a) 09/28/2017 Mohs map - Layer I; quadrisected, each of the four pieces were frozen and processed on four separate chucks. The Mohs map indicated red markings identifying residual tumor in pieces two and three. There were no red markings indicating residual tumor in pieces one and four. There were no results for the residual tumor indicated in red for pieces two and three nor results for the lack of residual tumor for pieces one and four. Layer II; frozen and processed on one chuck. The Mohs map indicated red markings identifying residual tumor in the sole piece. There was no result for the residual tumor indicated in red. The final test report (Operative Note) revealed the following chart: "Stage 1 2 3 Sections 4 1 1 Result by Stage + + - (-); All margins free of tumor (+); Positive margin - see attached MOH's map ...The

	tumor was removed by MOHs surgery, fresh technique in 3 stages, with 6 pieces of tissue were processed...stained...examined...At the completion of the procedure, all final surgical margin sections were free." b) 02/05/2018 Mohs map - Layer I; bisected, each of the two pieces were frozen and processed on two separate chucks. The Mohs map indicated red markings identifying residual tumor in pieces one and two. There were no results for the residual tumor indicated in red for pieces one and two. Layer II; bisected, each of the two pieces were frozen and processed on two separate chucks. The Mohs map indicated red markings identifying residual tumor in pieces three and four. There were no results for the residual tumor indicated in red for pieces three and four. The final test report (Operative Note) revealed the following chart: "Stage 1 2 3 Sections 2 2 1 Result by Stage + + - (-); All margins free of tumor (+); Positive margin - see attached MOH's map ...The tumor was removed by MOHs surgery, fresh technique in 3 stages, with 5 pieces of tissue were processed...stained...examined...At the completion of the procedure, all final surgical margin sections were free." c) 03/19 /2018 Mohs map - Layer I; bisected, each of the two pieces were frozen and processed on two separate chucks. The Mohs map indicated red markings identifying residual tumor in pieces one and two. There were no results for the residual tumor indicated in red for pieces one and two. Layer II; bisected, each of the two pieces were frozen and processed on two separate chucks. There were no red markings indicating residual tumor in pieces three and four. There was no result for the lack of residual tumor for piece three. There was a hand written "Clear" next to piece four. The final test report (Operative Note) revealed the following chart: "Stage 1 2 Sections 2 2 Result by Stage + - (-); All margins free of tumor (+); Positive margin - see attached MOH's map ... The tumor was removed by MOHs surgery, fresh technique in 2 stages, with 4 pieces of tissue were processed...stained...examined...At the completion of the procedure, all final surgical margin sections were free." 3. The Laboratory Director, OM and HP confirmed the Mohs test reports did not indicate the test result for each test (stage /layer and piece) of tissue tested. The interviews occurred on 04/10/2018 at 1:15 PM.