Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0910503	06/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laser And Skin Surgery Center, The	29101 Health Campus Dr, Ste 300, Westlake, 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: **This is a repeat deficiency as cited on the routine onsite 08/29/2017 CLIA inspection.** Based on direct observation of the Histopathology laboratory on the date of the inspection at 1:15 PM and interviews with the Laboratory Director and Histopathology processor (HP) #1, the laboratory failed to accurately label the only secondary container of Covermount with the correct lot number and expiration date. All patient Moh's testing procedures from 05/01/2018 to the date of the inspection had the potential to be affected by this deficient practice. Findings Include: 1. Direct observation of the histopathology laboratory on 06/18/2019 at 1:15 PM, found one secondary squeeze bottle labeled as Covermount; lot number 45902 with an expiration date of 04/18. 2. The Inspector requested the stock container of Covermount currently in use from HP#1. HP#1 provided an opened, in-dated and currently in use stock container of Covermount of a different lot number. 3. The Laboratory Director and HP#1 stated the laboratory poured the Covermount from the stock bottle into the secondary squeeze bottle and confirmed the laboratory did not accurately re-label the secondary squeeze bottle with the correct lot number and expiration date when the new Covermount supply was put into use. The interview occurred on 06/18/2019 at 1:15 PM.
D5787	TEST RECORDS CFR(s): 493.1283(a)

	The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Item 1: Based on record review and interviews with the Laboratory Director and Histopathology processor (HP) #1, the laboratory, in 2018, failed to positively identify two out of 213 patient Moh's cases, performed on different days, with their own unique accession numbers on all of the slides and on the Moh's maps of both cases. Findings Include: 1. Review of the laboratory's Moh's log, Moh's maps and Moh's Procedure Note/final test reports for 213 patient Moh's cases performed in 2018, provided on the date of the inspection, revealed two patient Moh's cases; one performed on 11/14/2018 and the other on 11/28/2018. Both of the Moh's maps and all of the slides of both cases were labeled with the identical accession number (M-195-18). Additionally, the patient Moh's testing performed on 11/14/2018 was not listed on the laboratory's Moh's log. 2. The Laboratory Director and the HP#1 confirmed the clerical errors on all of the slides and Moh's maps from two Moh's cases, as stated above and the lack of positive and unique identification of both of the patients' specimens. The interviews occurred on 06/18/2019 at 2:40 PM. Item 2: Based on record review and interviews with the Laboratory Director and Histopathology processor (HP) #1, the laboratory failed to have an accurate test record system in which the Moh's log reflected the accurate stage/layer and the number of tissue pieces in each stage/layer for 12 out of 213 Moh's cases in 2018 and six out of 89 Moh's cases in 2019. Findings Include: 1. Review of the laboratory's 2018 and 2019 Moh's log, Moh's maps and Moh's Procedure Note/final test reports revealed missing or inaccurate information regarding the stage/layer and/or number of pieces in each stage/layer as listed below: Date of Moh's Log Moh's Map Procedure Moh's Notes Procedure Stage/Layer Stage/Layer Stage/Layer and pieces and pieces and pieces 01/10/2018 4/3/3 4/3/3/2 4/3/3/2 08/29/2018 1/1 1/1/1 1/1/1 09/12/2018 1 1 /1 1/1 09/12/2018 1 4 4 09/26/2018 7/1 6/1 6/1 10/31/2018 1/1 1/2 1/2 11/07/2018 1/2 1/2/1 1/2/1 11/14/2018 1 2 1 11/14/2018 1/1 1/1/1 1/1/1 11/14/2018 1 1/2 1/2 11/14 /2018 not on log 1/1 1/1 12/05/2018 2/1 2/1/1 2/1/1 01/09/2019 2/1/2 2/1 2/1 01/23 /2019 1/1/1 1/1 1/1 02/06/2019 1 1/1/1 1/1/1 03/13/2019 1/2 2/2 2/2 03/27/2019 1 2 2 05/01/2019 1 1/1 1/1 2. The Laboratory Director and HP#1 confirmed the clerical errors in the test records. The interviews occurred on 06/18/2019 at 2:40 PM.
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: Item 1: Based on record review and interviews with the Laboratory Director and Histopathology processor (HP) #1, the laboratory failed to accurately record the test result for the last stage/layer in the Procedure Note/final test report for one out of 213 patient Moh's cases performed in 2018. Findings Include: 1. Review of the laboratory's Moh's maps for 213 patient Moh's cases performed in 2018, provided on the date of the inspection, revealed a patient Moh's procedure conducted on 11/07 /2018 that progressed to three stages/layers to finally accomplish a tumor free margin in stage three, piece/section four with the hand written result interpretation "Negative 'Laboratory Director's signature'". 2. Review of the Procedure Note/final test report found the following result interpretation of the third and last stage/layer: "Third Stage:...residual SCCA in situ was noted at the epidermal margins." 3. The Laboratory Director and HP#1 confirmed the result interpretation on the Mohs map was correct and the result on the Procedure Note/final test report was incorrect, as stated above. The interviews occurred on 06/18/2019 at 2:40 PM. Item 2: Based on record review and interviews with the Laboratory Director and Histopathology processor (HP) #1, the laboratory failed to accurately record the stage/layer of one out of 213 patient Moh's cases in 2018, from the Moh's map to the Procedure Note/final test report. Findings Include: 1. Review of the laboratory's 2018 Moh's log, Moh's maps and Moh's Procedure Note/final test reports found a patient Moh's case performed on 11/14 /2018 that indicated one gross piece from stage/layer I on the Moh's log, two gross pieces from stage/layer I on the Moh's map and one gross piece from stage/layer I on the Moh's Procedure Note/final test report. 2. The Laboratory Director and HP#1 confirmed the stage/layer and number of gross pieces were correctly indicated on the Moh's map and the Moh's Log and Moh's Procedure Note/final test report were incorrect, as stated above. The interviews occurred on 06/18/2019 at 2:40 PM. Item 3: Based on record review and interviews with the Laboratory Director and Histopathology processor (HP) #1, the laboratory, in 2018, failed to accurately record the specimen source for one out of 213 patient Moh's cases on the Moh's Procedure Note/final test report. Findings Include: 1. Review of the laboratory's Moh's maps and Moh's Procedure Note/final test reports for 213 patient Moh's cases performed in 2018, provided on the date of the inspection, revealed on 11/14/2018 a patient Moh's Map indicated the specimen source as the left elbow, which had a line through "elbow" with "forearm" hand written next to it. The Moh's Procedure Note/final test report indicated the specimen source as the "left elbow". 2. The Laboratory Director and HP#1 confirmed the Moh's specimen was from the left forearm as well as the specimen source clerical error on the Moh's Procedure Note/final test report, as stated above. The interviews occurred on 06/18/2019 at 2:40 PM.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director and Histopathology Processor (HP) #1, the Laboratory Director failed to ensure that the quality assessment program was established and maintained to assure the quality of the high complexity Moh's testing procedures performed and to identify failures in

	quality as they occur. All patient testing from 08/29/2017 to current had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Policy and Procedure for Lab Systems Quality Assessment:" policy and procedure, provided on the date of the inspection, approved via signature and date by the Laboratory Director, found a hand written note stating that the quality assessment policy and procedure was discontinued as of 08/29/17. 2. The Inspector requested the laboratory's ongoing quality assessment policy and procedure and documentation of these activities from the last CLIA inspection in 08/2017 to current for the high complexity Moh's testing procedures performed from the Laboratory Director and HP#1. The Laboratory Director stated that the laboratory may have misunderstood a recommendation from the CLIA inspection in 08/2017 and confirmed the quality assessment policy and procedure provided on the date of the inspection had been discontinued as of 08/29/2017, the laboratory did not establish, follow and document any other quality assessment activities for all phases of the Moh's testing procedures performed and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 06/18/2019 at 3:05 PM.