

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0910503	(X3) Date Survey Completed 07/10/2023
Name of Provider or Supplier Laser And Skin Surgery Center, The	Street Address, City, State 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
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Item 1: **This is a repeat deficiency as cited on 06/18/2019** Based on record review and interviews with the Laboratory Director and the Histology Processor (HP), the laboratory failed to have an adequate manual system in place to ensure test results were accurately recorded between the MOHs map and the Procedure Note (final test report) for each section/stage of tissue biopsy tested for five out of 10 randomly chosen patient MOHs cases reviewed out of 522 MOHs cases performed from 11/24 /2021 through 07/10/2023. Findings Include: 1. Review of the laboratory's MOHs maps and Procedure Notes for 10 randomly chosen patient MOHs cases, provided on the date of the inspection, revealed the following five cases as evidence showing the lack of accurate reporting: Case 1 Date: 05/04/21 MOHs map: section "23" Procedure Notes: section "25" Case 2 Date: 02/21/23 MOHs map: section "10" Procedure Notes: section "8" Case 3 Date: 04/18/23 MOHs map: II Stage; section "2" and section "3" Procedure Notes: Second Stage; "...provided 1 gross section..." Case 4 Date: 05/02/23 MOHs map: "IV" Stage; 1 section; piece "5...negative"; no V Stage indicated Procedure Notes: "Fourth Stage"; "...provided one gross section...Histologic findings: positive" "Fifth Stage...provided one gross section...Histologic findings:the surgical margins were free of microscopic tumor..." Case 5 Date: 06/13/23 MOHs map: II</p>

Stage; sections "#3, 4, 5, 6 are negative for BCCA" Procedure Notes: Second Stage; "Histologic findings: residual infiltrative basal cell cancer was noted in the dermis at the deep margin." 2. The Laboratory Director and the HP confirmed the result interpretations on the MOHs map were correct and the results on the Procedure Note (final test report) was incorrect, as indicated above. The interviews occurred on 07/10/2023 at 11:20 AM. Item 2: **This is a repeat deficiency as cited on 06/18/2019**

Based on record review and interviews with the Laboratory Director and the Histology processor (HP), the laboratory failed to have an adequate manual system in place to ensure the specimen sources were accurately recorded for three out of 10 randomly chosen patient MOHs cases reviewed out of 522 patient MOHs cases performed between 11/24/2021 through 07/10/2023. Findings Include: 1. Review of the laboratory's MOHs maps and MOHs Procedure Note (final test reports) found the following patient MOHs cases with inconsistent specimen sources indicated: Case 1 Date: 05/04/21 MOHs map: "back of neck" Procedure Notes: "Neck" Case 2 Date: 01/25/22 MOHs map: "BCCA right postauricular ear" Procedure Notes: "BCCA on R post - auricular scalp" Case 3 Date: 05/02/23 MOHs map: "BCCA right lateral nasal wall" Procedure Notes: "Nose R nasal wall." 2. The Laboratory Director and HP confirmed the specimen sources lack consistency between the MOHs maps and the Mohs Procedure Notes (final test reports), as indicated above. The interviews occurred on 07/10/2021 at 11:20 AM.