

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2026992	(X3) Date Survey Completed 02/24/2022
Name of Provider or Supplier Cleveland Clinic Twinsburg Mohs Lab	Street Address, City, State 8701 Darrow Road, Twinsburg, 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Consultant (LC) and Histopathology Processor (HP), the laboratory failed to include all patient test result interpretations for all sections of tissue within each layer of tissue removed and tested on the final test report in the specialty of Histopathology. This deficient practice had the potential to affect 109 out of 109 patients tested in this laboratory from 09/30/2021 to 12/09/2021. Findings Include: 1. Review of eight out of eight of the laboratory's final patient test reports revealed three final test reports that did not indicate a test result for each section of tissue tested as follows: 10/13/2021 -layer A was "...subdivided into four sections...residual superficial and nodular BCC was identified in pieces A1, A2, A4." no result reported for A3 -layer B was "...subdivided into three sections...residual superficial, nodular and perifollicular BCC was identified in pieces B3." no results reported for B1 and B2 -layer C had "...one sections...no residual tumor was identified." 10/25/2021 -layer A was "...subdivided into 2 sections...residual superficial BCC was identified in pieces A1." no result reported for A2 -layer B had "...one sections...no residual tumor was identified." 10/28/2021 -layer A was "...subdivided into 2 sections...residual superficial BCC was identified in piece A2." no result reported for A1 -layer B had "...one sections...residual superficial BCC was</p>

identified in piece B1." -layer C had "...one sections...residual superficial and nodular BCC was identified in pieces C1." -layer D had "...one sections...no residual tumor was identified." 2. The LC and HP confirmed the laboratory did not indicate the test result for each section of tissue tested for three out of eight patients on the final patient test report. The interviews occurred on 02/24/2022 at 9:45 AM.