

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D1105263	<b>(X3) Date Survey Completed</b>  08/01/2023
<b>Name of Provider or Supplier</b>  Columbus Skin Surgery Center Inc	<b>Street Address, City, State</b>  6670 Perimeter Drive, Suite 260, Dublin, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5449</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview an with the Mohs Technician, the laboratory failed to document quality control (QC) for Hematoxylin and Eosin (H&amp;E) Mohs testing procedures for three out of 378 days of patient testing from 09/01/2021 through 08/01/2023. Sixteen out of 3,982 patients tested from 09/01/2021 through 08/01/2023 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Verification of H and E Performance Standard" policy and procedure found the following statement: "I verify that the established performance standards of a crisp, clear appearance of the Hematoxylin (purple) stain and the Eosin (pink) stain, clearly evident tissue structures, and clarity of the slide have been met for the follow QC slides that I have reviewed prior to testing patient specimens..." 2. Review of the laboratory's QC data from 09/01/2021 through 08/01/2023 found three out of 378 days that H&amp;E Mohs patient testing was performed without QC documentation. This deficient practice had the potential to affect 16 patients. 09/30/21 QC Patient 1 [none] Patient 2 [none] Patient 3 [none] Patient 4 [none] 12/23/2021 QC Patient 1 [none] Patient 2 [none] Patient 3 [none] Patient 4 [none] Patient 5 [none] Patient 6 [none] 06/16/2022 QC Patient 1 [none] Patient 2 [none] Patient 3 [none] Patient 4 [none] Patient 5 [none] Patient 6 [none] 3. The surveyor requested QC documentation of H&amp;E Mohs patient testing for the days 09/30/21, 12/23/2021 and 06/16/2022. 4. An interview with the Mohs Technician, on 08/01/2023 at 2:39 PM, confirmed that the laboratory failed to document QC of H&amp;E Mohs</p>

testing for the days 09/30/21, 12/23/2021 and 06/16/2022 which had the potential to affect 16 patients.