

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2264351	(X3) Date Survey Completed 12/01/2022
Name of Provider or Supplier Osu Dublin Mohs Laboratory	Street Address, City, State 6700 University Boulevard, 3rd Floor, Dublin, 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
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Ambulatory Point of Care Coordinator, the laboratory failed to establish and follow performance specifications to include accuracy, precision, analytical sensitivity, analytical specificity, interfering substances, reportable range of test results for the test system, reference intervals, and any other performance characteristic required for MOHS test procedures before reporting patient test results. All 126 patients tested at this laboratory, in the speciality of histopathology, beginning 08/29/2022, had the potential to be affected. Findings Include: 1. Review of the laboratory's policies and procedures failed to find a policy and procedure for conducting and establishing performance specifications for the MOHS testing procedures, implemented on 08/29/2022. 2. A review of the laboratory's documentation failed to find evidence of performance specifications of the MOHS test procedure prior to testing patient specimens and reporting patient results 3. An interview with the Ambulatory Point of Care Coordinator, on 12/01/2022 at 1:57 PM, confirmed the laboratory did not have a performance specification policy and procedure established, and failed to document performance specification activities</p>

for the MOHS test procedure, prior to testing patient specimens and reporting patient results.