

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1027924	(X3) Date Survey Completed 02/27/2024
Name of Provider or Supplier Dmg Dermatology Institute	Street Address, City, State 2155 City Gate Lane, Naperville, IL	
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
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with laboratory director (LD); the laboratory failed to document pathology immunohistochemical (IHC) staining positive and negative reactivity / quality control (QC) as required by 493.1256 for three of three patient IHC testing dates reviewed. Findings Include: 1. The laboratory's "City Gate MOHS Immunohistochemistry (MART-1)" procedure was reviewed and stated the following regarding IHC staining: "MART-1 positive control is cut and run prior to running patient tissue. Controls are collected and approved by Dr. Mehta. (and stored in freezer for future use)" 2. Review of patient testing results for three of three IHC stain testing dates found that no IHC staining positive and negative reactivity / QC was documented for these days of IHC stain testing. Report Date: Patient ID: Types of IHC Stain: 10/19/2022 SM22-1125 Mart 1 01/04/2023 SM23-11 Mart 1 07/11/2023 SM23-620 Mart 1 3. On 02/27/2024, at 02:40 pm, the LD confirmed the above findings.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform</p>

test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, CMS-209 (Laboratory Personnel Report), lack of documentation, and interview with a laboratory representative; the technical consultant failed to ensure competency evaluations for one of five testing personnel (TP) performing Provider-Performed Microscopy (PPM) at the laboratory testing facility in the years of 2022 and 2023. Findings include: 1. Review of the CMS-209 revealed five TP performing PPM testing of Potassium Hydroxide (KOH) and scabies. 2. Review of laboratory competency evaluation records revealed that one of five TP performing PPM testing lacked documentation of competency performed at the testing laboratory. 3. An interview with a laboratory representative on 02/27/2024, at 12:36 pm, confirmed the above findings.