

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1096052	(X3) Date Survey Completed 05/06/2021
Name of Provider or Supplier Skin & Laser Surgery Center	Street Address, City, State 1359 Beverly Road, Mclean, VA	
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
D0000	An announced off-site CLIA recertification survey was conducted for Skin and Laser Surgery Center on May 6, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on April 7, 2021 and virtual record review conducted on April 29, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), the laboratory's policy and procedures, peer review documentation, lack of documentation, and interviews, the laboratory failed to perform one (1) of two (2) annual Histopathology peer review in calendar year 2020. Findings include: 1. Review of the laboratory's CMS 116 form revealed one testing personnel (TP A) was identified as performing high complexity Histopathology during the twenty-eight months reviewed (January 2019 to April 2021). 2. Review of the laboratory's policies and procedures revealed a policy, "Test Comparison/Peer Review" which stated "Peer reviews are done yearly (at least two) to review slide interpretation with an independent laboratory. Document agreement or disagreement and corrective actions." 3. Review of the laboratory's verification of accuracy records from January 2019 to the date of survey revealed one (1) MOHS accuracy verification was performed and evaluated in calendar year 2020 (recorded on 01/23/2020). The inspector requested documentation of additional verification of</p>

accuracy in 2020. The laboratory provided no additional documentation for review. 4. In an exit interview with the Mohs Technician on May 6, 2021 at approximately 11:10 AM, the above findings were confirmed.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure manual, "Cryostat Temperature and Staining Chemical log", Log Sheet for Mohs Surgery and interview, the laboratory failed to document the intended reactivity for Hematoxylin and Eosin (H&E) stain for five (5) days from January 1, 2019 until April 21, 2021 while reporting six (6) patients. Findings include: 1. Review of the procedure manual revealed a policy, "Quality Control" which states: "The Laboratory Director reviews all quality control and it is logged on a daily basis." 2. Review of the "Cryostat Temperature and Staining Chemical log" from January 1, 2019 until April 21, 2021 revealed no H&E slide QC review for the following dates: 09/20/2019 - 1 patient; 01/03/2020 - 1 patient; 05/06/2020 - 2 patients; 06/05/2020 - 1 patient; 06/19/2020 - 1 patient. A total of 6 patients. 3. In an interview with the Mohs Technician on May 6, 2021 at approximately 10:10 AM, the surveyor asked the Mohs Technician to provide evidence of an H&E QC slide for the dates listed above. The Mohs Technician stated they do not have QC slides for the dates listed above.