

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2289133	(X3) Date Survey Completed 04/12/2024
Name of Provider or Supplier Green Dermatopathology	Street Address, City, State 7101 Hunters Chase, Norfolk, 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 CLIA initial survey was conducted at Green Dermatopathology on April 11, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The inspection also included an offsite follow up interview with the lab director on 4/12/24. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
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 a review of the laboratory's Centers for Medicare and Medicaid Services (CMS) Aspen database and CMS survey 116 form, patient test logs, lack of documentation, and interviews, the laboratory failed to ensure that dermatopathology test reports included the correct performing laboratory name and address for ten (10) of 10 patient reports randomly selected for review during the initial survey on April 11, 2024. Findings include: 1. During pre-survey inspection duties, the inspector noted that the CMS Aspen database listed the laboratory's name and physical facility location as: Green Dermatopathology 7101 Hunters Chase Norfolk, Virginia 23518 CLIA ID 49D2289133 Review of the laboratory's submitted CMS 116 form confirmed the above name and address. 2. Review of the laboratory patient test logs from a randomly selected specimen receipt date timeframe of 2/14/24 to 2/29/24</p>

revealed sixty dermatopathology cases. The inspector requested to review the following 10 selected dermatopathology test results (accession/case numbers) from the selected timeframe: AD24-1758, AD24-1781, AD24-1783, AD24-1785, AD24-1789, AD24-1791, AD24-1792, AD24-1838, AD24-1839, AD24-1840. The inspector's review revealed that the selected patient reports failed to identify the correct performing laboratory name/physical location for the dermatopathology microscopy evaluation. The inspector noted the reports included a footnote "performing labs" with the following information: Annapath, INC Component Type - Technical Processing 4801 Tesla Drive, Suite H Bowie, MD 20715 CLIA 21D1057101 3. The inspector inquired in a follow up interview regarding the performing laboratory footnote outlined above. The laboratory director (LD) confirmed on 4/11/24 at 5:30 PM that all one hundred ninety two (192) patient case reports (timeframe-January 2024 to date) failed to correctly identify the dermatopathology evaluation component's performing laboratory name/physical location. 4. An offsite follow up interview with the LD on 4/12/24 at 9:30 AM confirmed the above findings.