

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2240067	(X3) Date Survey Completed 08/28/2024
Name of Provider or Supplier Neogenomics Laboratories Inc	Street Address, City, State 1355 N Scottsdale Rd Ste 150, Scottsdale, AZ	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the test procedure for Flow Cytometry testing and interview with the facility personnel, the laboratory failed to have the current laboratory director approve, sign and date the test procedure before use. Findings include: 1. The current laboratory director indicated in the CLIA Federal Database and assigned on the CMS-209, Laboratory Personnel Form presented for review during the survey has been listed as laboratory director on CLIA# 03D2240067 since 01/31/2023. 2. The test procedure, "CD4-CD8 Ratio for BAL Flow Panel" presented for review during the survey conducted on 8/28/2024 was not approved, signed and dated by the current laboratory director. 3. The facility personnel interviewed on August 28, 2024 at 11:10 AM confirmed the test procedure indicated above was not approved, signed and dated by the current laboratory director before use. 4. The laboratory began patient testing in the subspecialty of General Immunology on 2/15/2023, with an annual test volume of 16.</p>