

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0948425	(X3) Date Survey Completed 08/15/2024
Name of Provider or Supplier Lysosomal Diseases Testing Laboratory	Street Address, City, State 1020 Locust Street Room 346, Philadelphia, PA	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to perform and document the maintenance and function checks as defined by the manufacturer for 1 of 1 Enviroco Fume Hood used for Chemistry testing performed in 2021, 2022 and 2023. Findings include: 1. On the day of survey 08/15/2024 the laboratory could not provide maintenance/function check records 1 of 1 Enviroco Fume Hood (serial number 9210063) used for Chemistry testing performed in 2021, 2022 and 2023. 2. LD confirmed the findings above on 08/15/2024 at 10:25 am.</p>