GRANGER		Specimen Information
	G2500036	Date Collected: 01/03/2025 Date Received: 01/03/2025 15:46
601 Biotech Dr. Suite 301 Richmond, VA 23235Phone:ww.grangergenetics.comFax:	(844) 347-2643 (804) 977-5041	Date Reported: 01/30/2025 15:56 Date of Last Injection:
Patient Information		Physician Information
Name: TEST	Physician Test	
Date of Birth: 05/15/2023 Age: 1Y Gender: M Patient MRN: TEST Sample ID: CPT Codes: 83516, 83520	Test Agency 601 BioTech Dr Su North Chesterfield, (844) 347-2643	
Glucarpidase Antibodies		
Screening Antibodies Reference Range = 0 ng/mL		85.459 ng/mL
Screening Interpterion		Positive
Neutralizing Antibodies Results		Positive
Assay Methodologies and Limitations of Glucarpidase		

The Glucarpidase antibody screening assay is an ELISA based assay and reports the presence or absence of antibodies against Glucarpidase in addition to the antibody concentration. This assay does not specifically identify neutralizing antibodies. Samples testing positive for Glucarpidase antibodies are subsequently assayed for neutralizing antibodies. Antibodies should not be present in normal human serum but may be present in patients dosed with Glucarpidase.

The Glucarpidase neutralizing antibody assay is a reflex assay that is only performed on samples testing positive for Glucarpidase antibodies in the screening assay. This assay utilizes an enzyme activity assay to indirectly determine if neutralizing antibodies are present. The presence of neutralizing antibodies result in an inhibition of enzyme activity.

These tests were developed and their performance characteristics determined by Granger Genetics. Neither assay has been cleared or approved by the FDA. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.