



### Specimen Information

G2500034

Date Collected: 01/03/2025

Date Received: 01/03/2025 15:34

Date Reported: 01/30/2025 15:36

Date of Last Injection:

601 Biotech Dr. Suite 301 Richmond, VA 23235

Phone: (844) 347-2643

ww.grangergenetics.com

Fax: (804) 977-5041

### Patient Information

Name: **TEST**

Date of Birth: 05/15/2023 Age: 1Y Gender: M

Patient MRN: TEST

Sample ID:

CPT Codes: 83516

### Physician Information

**Physician Test**

Test Agency

601 BioTech Dr Suite 301

North Chesterfield, VA 23235

(844) 347-2643

### Glucarpidase Antibodies

Screening Antibodies

<31.3 ng/mL

Reference Range = 0 ng/mL

Screening Interpretation

Negative

### 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.