labcorp

Please complete this Test Requisition Form in English

Sanofi Rare Disease
Specialty Testing Program
Royal Children's Hospital
4th Floor, East Building
50 Flemington Road
Parkville, Victoria 3052 Australia
61 3 9345 9806

Send additional copy of report to:
☐ Fax _____ ( )_____

Account # 76001080

Account Bill Only

Patient's Legal Name (Last, First, MI) | Sex ☐ M ☐ F | Date of Birth MO DAY YEAR | Collection Time : ☐ AM ☐ PM | Collection Date MO DAY YEAR

Clinician or Physician's / Authorized Name (Last, First)

Clinician or Physician's / Authorized Signature

x _____

Patient's ID #

Please check applicable treatment

☐ Aldurazyme®
☐ Cerezyme®
☐ Fabrazyme®
☐ Myozyme®
☐ Nexviazyme®/ *Nexviadyme®

Test Category: Adverse Event Hypersensitivity

Mark requested testing below:

☐ 504762 Laronidase (Aldurazyme) IgE Antibody
☐ 504758 Imiglucerase (Cerezyme) IgE Antibody
☐ 504754 Agalsidase beta (Fabrazyme) IgE Antibody
☐ 504766 Alglucosidase alfa (Myozyme) IgE Antibody
☐ 504880 Avalglucosidase alfa (Nexviazyme/Nexviadyme) IgE Antibody
☐ 504775 Complement Activation: C3a
☐ 504779 Mast Cell Activation Serum Tryptase

Sample Requirements:

Test Type	Collection Tube	Sample Type / Volume	Submission Tube	Sample Storage	Sample Stability	Shipping Temperature
Anti-drug IgE Antibody	Serum Separator Tube or Red Top	1 mL Serum	Transfer Tube	Preferred: ≤ -20°C (Frozen) Acceptable: 2°C to 8°C (Refrigerated)	Frozen: 24 months Refrigerated: 14 days	Frozen
Complement Activation	Lavendar (K2EDTA) top	1 mL Serum	Transfer Tube	≤ -20°C (Frozen)	1 month Do not allow sample to thaw	Frozen
Serum Tryptase	Serum Separator Tube or Red Top	1 mL Serum	Transfer Tube	Preferred: ≤ -20°C (Frozen) Acceptable: 2°C to 8°C (Refrigerated)	Frozen: 24 months Refrigerated: 14 days	Frozen

Testing for drug-specific IgE antibody, complement activation and tryptase may be warranted for patients who experience an infusion-associated reaction suspected to represent a Type 1 (IgE mediated) hypersensitivity reaction. Samples for complement activation and tryptase should be collected 1-3 hours after onset of reaction whereas samples for drug-specific IgE antibody should be collected at least 3 days after infusion or prior to subsequent infusion.

For questions, please contact the LabCorp Project Manager at RareDiseaseProgram@labcorp.com.

*Nexviadyme is only available in Europe.

Adverse events suspected to be associated with laronidase (Aldurazyme), imiglucerase (Cerezyme), agalsidase beta (Fabrazyme), alglucosidase alfa (Myozyme), and avalglucosidase alfa (Nexviazyme/Nexviadyme) should be reported directly to Sanofi Pharmacovigilance.