IMMUNOTESTING SERVICES - HCP GUIDE

Nexviazyme® (avalglucosidase alfa)

Guidance for health care professionals on immunology testing services provided with Nexviazyme® administration

Version 1 <February> <2023>

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ABBREVIATIONS

AE	Adverse Event
GP	Global Pharmacovigilance
HCP	Health Care Professional
IAR	Infusion-Associated Reaction
ADA	Antidrug Antibodies
SmPC	Summary of Product Characteristics

1. OBJECTIVES AND GOALS

Aims of the Immunotesting services guide

Nexviazyme® (avalglucosidase alfa) treatment should be supervised by a physician experienced in the management of patients with Pompe disease or other inherited metabolic or neuromuscular diseases.

The Nexviazyme® Immunotesting services guide is part of the educational materials provided to physicians involved in managing patients with Pompe disease treated with Nexviazyme®. Treating physicians may make this material available to other health care professionals (HCPs) involved in the management of the disease as required. The main purposes of the Immunotesting service guide are to:

1. Guide HCPs to carry out immunological testing which will help to further characterize the potential mechanism of infusion-associated reactions (IARs) and hypersensitivity reactions, and appropriately manage patients experiencing loss of treatment response due to antidrug antibodies (ADA).
2. Provides information on the Sanofi Rare Disease Specialty Testing program, for immunological testing practicalities.

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2. KEY CONTACTS

- **For information how to access Sanofi Rare Disease Specialty Testing program or other test-related questions for Nexviazyme®**:

  Please contact Medical Services Department, Gulf Medical-Information /AE

  E-mail: Medical-Information.Gulf@sanofi.com

- **For medical information regarding Pompe Disease or Nexviazyme®:**

  Please contact Medical Information Department via email: Medical-Information.Gulf@sanofi.com

3. Testing Recommendations

This current testing service described in this HCP guide is part of Sanofi Rare Disease Specialty Testing programthrough LabCorp. It provides a complimentary offer of testing: anti-drug IgG antibody, adverse event related immunogenicity testing and biomarker testing services for patients with Pompe Disease and other rare disease. This is a service offered to the HCPs which can be also managed through a local laboratory for some of the testing.

Testing recommendations for Nexviazyme®:

- Baseline serum sample collection prior to the first infusion is strongly encouraged.
- IgG antibody titers should be regularly monitored, and IgG ADA testing should be considered if patients do not respond to therapy
    - Treated patients may be tested for inhibitory antibodies if they experience a decrease in clinical benefit despite continued treatment with Nexviazyme®
- Adverse-event (AE)-driven immunologic testing, including IgG and IgE ADA, should also be considered in patients who experience moderate/severe or recurrent IARs suggestive of hypersensitivity reactions, anaphylactic reactions.
- AE-driven immunologic testing should be considered for patients at risk for allergic reaction or previous anaphylactic reaction to Myozyme® (alglucosidase alfa).

Please refer to the locally approved prescribing information in the SPC or PIL for further information

4. Testing practicalities

4.1 Description of the immunotesting services

A list of the immunogenicity testing offered (free of charge) with Nexviazyme® treatment through the Sanofi Rare Disease Specialty Testing program with Labcorp is provided in table 1. Detailed sample collection and submission information will be provided upon account set-up with LabCorp.

Table 1. Clinical immunology testing characteristics.

Test	Indication for testing	Sample Type	Frequency	Collection Time[a]
IgG	Routine monitoring	Serum-Frozen Whole blood (received within 24 hours of collection)	Routine monitoring	Sample should be Pre-infusion or ≥3 days post infusion
IgG/inhibitory antibody	Decreased response to treatment or lack of effect	Serum-Frozen Whole blood (received within 24 hours of collection)	Ad hoc (as needed)	Sample should be Pre-infusion or ≥3 days post infusion
IgG/IgE antibody	Moderate/severe or recurrent IARs suggestive of hypersensitivity reactions, anaphylactic reactions	Serum-Frozen Whole blood (received within 24 hours of collection)	Ad hoc (as needed)	Pre-infusion or at least ≥3 days post infusion
Serum Tryptase	Moderate/severe or recurrent IARs suggestive of hypersensitivity reactions, anaphylactic reactions	Serum-Frozen	Ad hoc (as needed)	1-3 hours post infusion reaction
Complement Activation	Moderate/severe or recurrent IARs suggestive of hypersensitivity reactions, anaphylactic reactions	EDTA Plasma-Frozen	Ad hoc (as needed)	1-3 hours post infusion reaction

4.2 Procedure to access the Immunotesting services

The procedure described in Figure 1 applies to all tests performed as part of an adverse event investigation (including IgG antibody, IgE antibody, inhibitory antibody, complement activation), and to all samples for routine IgG monitoring. Please contact your local Sanofi representative or Sanofi Medical Services via e-mail at Medical-Information.Gulf@sanofi.com for further information on how to access Sanofi Rare Disease Specialty Testing program.

Figure 1. Procedure to use the Sanofi Rare Diseases Specialty testing program

5 STEPS INSTRUCTIONS FOR PHYSICIANS REQUESTING SPECIALTY DIAGNOSTIC TESTING SERVICES

Sanofi Genzyme is coordinating and supporting this Rare Disease specialty testing program and is not otherwise involved in the diagnostic testing.

1

Sign statement 'Provision of Specialty Diagnostic testing Services by Sanofi Genzyme'

2

Enroll with LabCorp – complete account setup form

3

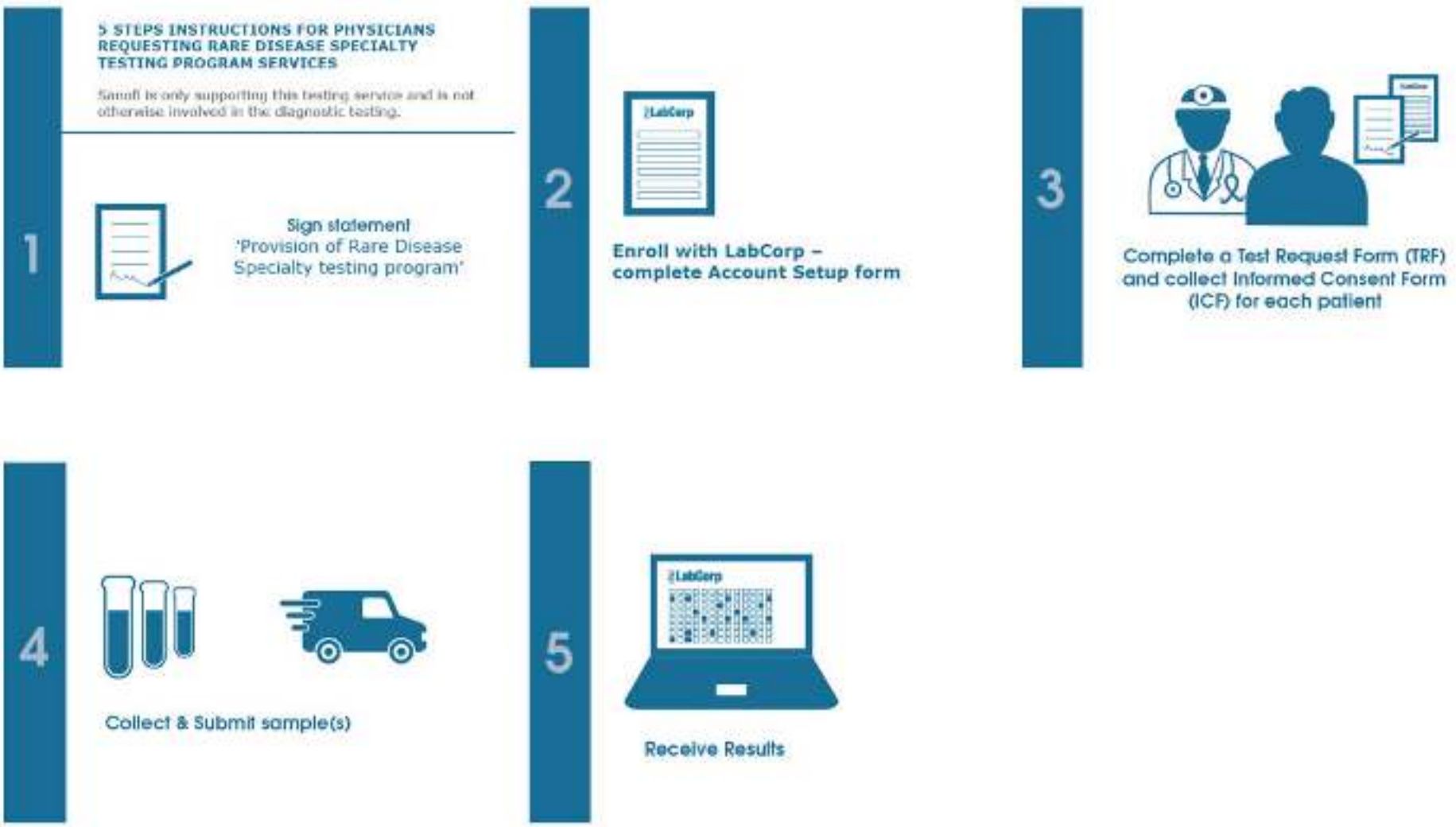
Complete a Test Request Form (TRF) and collect an Informed Consent Form (ICF) for each patient

4

Collect & submit sample(s)

5

Receive results



Sample requirements are listed in table 1. Labels for the submission tubes will be provided. Please ensure sample submission tubes are labeled with patient name, date of collection, test requested, and sample type and can be matched to the completed TRFs. Unlabeled or improperly labeled tubes may delay testing and availability of the results.

Marken is the preferred sample transportation and logistics service provider for the program. Marken starter pack will be provided electronically following the LabCorp account setup. A hardcopy of the Marken starter pack and the labels for the submission tubes will also be shipped to your location. The starter pack contains shipment procedures (e.g., Pickup requests, Sample packaging) and corresponding documentation (e.g., Invoice, Airwaybill).

Samples will be delivered to LabCorp in the United States within 14 days of pickup. For adverse event testing, expedited shipping is available and can be requested through Marken when scheduled sample pickup,

Please refer to the program In-service documents in appendix 1

5. Reporting adverse events

Reporting AE after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. HCP are asked to report any suspected adverse reactions.

To report adverse event(s) (AE) occurring in association with the use of Nexviazyme®, please contact:

The National Pharmacovigilance Center (NPC)
Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa/

And SANOFI Pharmacovigilance:
Phone: +966-544-284-797
E-mail: Ksa_pharmacovigilance@sanofi.com

Appendix 1

27562 Sanofi Rare
Disease In Service Document Non-biomarker (INT)_FINAL.pdf

27564 Sanofi Rare
Disease Test List Flyer Non-biomarker (INT)_FINAL.pdf

27566 Sanofi Rare
Disease Flyer Non-biomarker (INT)_FINAL.pdf

27802 Sanofi Rare
Disease Account Setup Form Non-Bio (INT)_FINAL.pdf