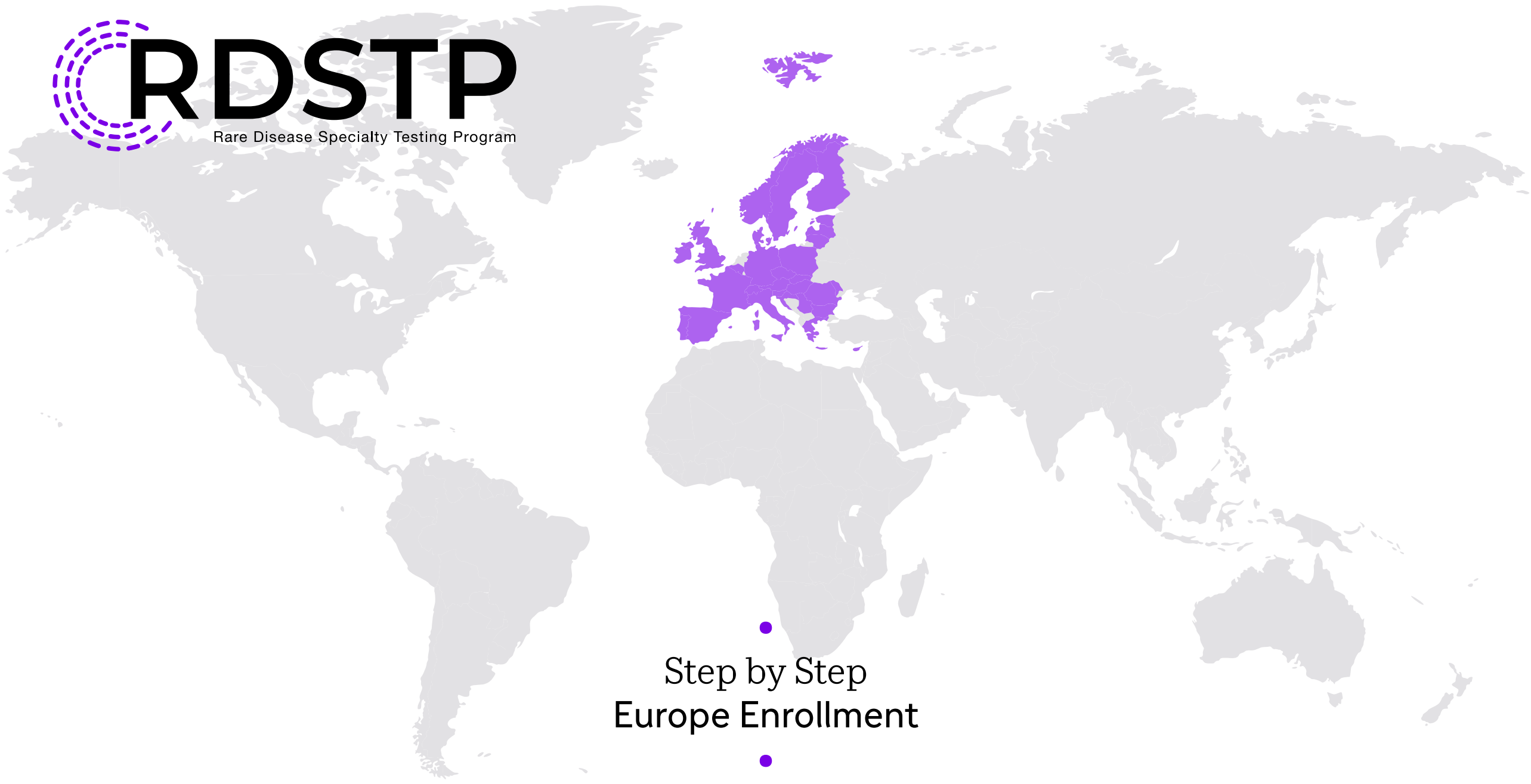


RDSTP

Rare Disease Specialty Testing Program



Step by Step
Europe Enrollment



*Comprehensive list of
countries within
Europe:*

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Moldova
Norway
Poland
Portugal
Romania
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
United Kingdom

If you are interested in enrolling in our program, please complete the following steps:

1. Step
one

Labcorp
Account Setup

2. Step
two

In-Servicing

3. Step
three

Test Ordering

4. Step
four

Sample Pickup

5. Step
five

Results Delivery

Rare Disease Specialty Testing Program • Europe

Step 1: Labcorp Account Setup

Health care professionals must obtain a Labcorp account that is specific for the Rare Disease Specialty Testing Program by:

- Completing Labcorp's online account setup form at:
<https://www.labcorp.com/account-setup-international-providers>

or

- Completing Labcorp's PDF account setup form and forwarding it to:
rarediseaseprogram@labcorp.com
- If you need any help completing the account setup form, or need additional assistance throughout the process, email: rarediseaseprogram@labcorp.com

Rare Disease Specialty Testing Program
Account setup form

Facility details

Facility name: _____ Facility phone (include country code): _____
Facility postal (street) address: _____ Town/City: _____
State/province: _____ Postal code: _____ Country: _____
Facility contact name: _____ Facility contact email address: _____

If the facility is a reference laboratory that will report to its ordering clinician(s), please provide the full name of the laboratory director.
Laboratory director name: _____
Otherwise, please provide the full names of the ordering clinician(s) below:
Clinician name: _____ Clinician name: _____
Clinician name: _____ Clinician name: _____

Testing (please check the type that may be ordered)

Anti-Drug IgG Antibody Adverse Event Hypersensitivity Adverse Event Neutralizing Antibody Biomarkers

Sample submission details

Other than the location previously provided, are there other locations where Marken will pick up samples for this program?

Results (please select your preferred method for result delivery)

Axiolink (provide fax number including country code): _____
 Labcorp Link™ online portal (please provide names and email addresses for any Labcorp Link users that require setup)



Please allow 7 - 10 business days from receipt of a completed form for account setup. Please send the completed form directly to Labcorp through email to RareDiseaseProgram@labcorp.com or fax to +1-855-224-0888.

Contact Labcorp with any questions regarding account setup through email at RareDiseaseProgram@labcorp.com.

By creating an account, I certify that we are not listed on any sanctions list published by the U.S. Departments of Commerce, Treasury, or State, including, but not limited to, the **Specially Designated Nationals and Blocked Persons list** and the **Denied Persons list**.

The information you provide on this form will be used to create the Labcorp account under which testing services for the Sanofi Rare Disease Specialty Testing Program will be placed and results delivered. You have a right to access, rectify or have your personal data deleted and you have the right to withdraw your consent at any time. In order to exercise this right or if you have any questions, please contact our privacy officer by e-mail at privacyofficer@labcorp.com. Labcorp's privacy policy can be found by visiting <https://www.labcorp.com/privacy-policy>.

Facility contact signature: _____ Date: _____
Required

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Rare Disease Specialty Testing Program • *Europe*

Step 1:

Additional Information

- The cost of testing and the cost of sample transport are covered by Sanofi.
- Samples can be collected and stored frozen during account setup. Facilities can obtain sample collection instructions by sending a request to Labcorp at: rarediseaseprogram@labcorp.com or Sanofi MSLs can share the approved test list flyer for their country.
- If a reference laboratory is the account holder they must have a valid export license.
- If there is an urgent need to expedite account setup (e.g., adverse event samples) please ask the facility submit an account setup form and then request expedited account setup by emailing Labcorp Program Management at: rarediseaseprogram@labcorp.com

Rare Disease Specialty Testing Program • *Europe*

Step 2: *In-Servicing*

Within *10-15 business days* of the completion of the account setup, Labcorp will send detailed program information to all email addresses provided on the Account Setup Form, including:

- Test Requisition Form (TRFs).
- Sample pickup instructions.
- Sample collection guidelines.

After receiving the in-service information from Labcorp, Marken will dispatch a Starter Pack within *7 to 10 business days*. This pack will contain detailed information about specimen pick-up and courier services.

Additional Information


Step 2: In-Servicing

All *In-Servicing* documents will be sent electronically in PDF format. The only hardcopy document that will be shipped is the Marken Starter Pack.

If a facility hasn't been in-serviced and it has been more than *10 business days*, or if a facility has NOT received their Marken starter pack but has been in-serviced by Labcorp please ask the facility to email [*rarediseaseprogram@labcorp.com*](mailto:rarediseaseprogram@labcorp.com) directly. If you prefer to contact Labcorp on the facility's behalf, please be sure to also copy the provider/facility and include enough information about the account (e.g., name of institution, country, provider name).

For Marken starter pack make sure to also address the e-mail to the appropriate Marken representative:

- Europe
[*sangen.ham@marken.com*](mailto:sangen.ham@marken.com)
- Please feel free to copy
- [*rarediseaseprogram@labcorp.com*](mailto:rarediseaseprogram@labcorp.com)



Step 3: *Test Ordering*

Health care providers must complete the appropriate Test Requisition Form (TRF) according to each patient.

Note that depending on the tests to be ordered, you must have to complete the appropriate TRF for each patient.

Mandatory information that must be included: patient name, date of birth, sex, provider name, and test requested. Treatment must be marked for immunogenicity testing.

On the top of each TRF there is a spot named "send additional copy of report to" where the provider can chose to send a copy of the test result to another provider.

All health care providers can utilize their own supplies to collect samples, as long as Labcorp's requirements are met.

Rare Disease Specialty Testing Program • *Europe*

Step 4:

Sample Pickup

With *2 business days* notice, Marken will pick up the samples at a requested date and time. To request pickup, providers will call their local Marken office or fax/email a completed booking form to their local Marken office.

Facility will need to package samples and corresponding TRFs (1 patient per biohazard bag) per instructions in the Marken starter pack, and provide a completed invoice and air waybill to the driver at pickup.

Samples will be shipped to regional hubs (e.g., Singapore, Hamburg, Miami) and batched for weekly shipment. Samples will be delivered to Labcorp in the United States within *14 business days* of pickup.

For adverse event testing, expedited shipping is available and can be requested when scheduling sample pickup.

Step 4:

Additional Information

- Samples collection supplies are not provided and must be obtained by the HCP/HCI. This program does not cover or provide support for the cost of office visits/evaluations or other testing unrelated to this specific program.
- At the time of pickup, Marken will provide all necessary packaging for samples transport (e.g., 95kPa transport bags, absorbent sheets, shipping box, dry ice).
- Users should check off the "adverse event" option on the booking form when coordinating sample pickup, enabling the shipment to be routed directly to the US. If calling for pickup, users should inform the Marken representative that the package include adverse events samples.

Step 5:

Results Delivery

Results can be delivered directly to the ordering healthcare provider (HCP) or reference laboratory via fax or Labcorp's online portal (www.labcorplink.com).



Additional Information

Step 5: Results Delivery

All turnaround times (TATs) do not include sample transport time. Samples collected outside of the US can take up to *14 business days* for delivery at Labcorp for testing.

TATs for testing: *14 business days* for routine testing, which includes anti-drug IgG Ab and biomarkers.

Adverse event testing are shipped as soon as possible on the next schedule flight option.

Labcorp offers expedited testing services for all tests, subject to specific conditions. For further details on expediting your test, please contact us at:
[*rarediseaseprogram@labcorp.com*](mailto:rarediseaseprogram@labcorp.com)

New option

For adverse event tests only, (e.g., anti-drug IgE antibody, anti-drug neutralizing antibody), Labcorp also provides results to Sanofi Global Pharmacovigilance within *24 hours* of test completion. If a suspected adverse event has not already been reported for the patient, Sanofi Global Pharmacovigilance team may contact the ordering health care professional for additional adverse event related information. Sanofi does not otherwise receive identifiable result reports from Labcorp.

