

Step by Step  
**Other Countries Enrollment**  
Spanish Version below English Version

*Detailed global list of*  
**Other Countries from around  
the world:**

Argentina  
Australia  
Brazil  
Canada  
Colombia  
Costa Rica  
Dominican Republic  
Ecuador  
Egypt  
El Salvador  
Guatemala  
Hong Kong  
India  
Israel  
Jordan  
Kuwait  
Lebanon  
Malaysia  
Mexico  
New Zealand  
Oman  
Peru  
Philippines  
Saudi Arabia  
Singapore  
South Africa  
South Korea  
Taiwan

Thailand  
Turkey  
United Arab Emirates  
Uruguay  
Vietnam  
Venezuela

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 • Other Countries

## 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](mailto:rarediseaseprogram@labcorp.com)
- If you need any help completing the account setup form, or need additional assistance throughout the process, email: [rarediseaseprogram@labcorp.com](mailto: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: \_\_\_\_\_  
Laboratory director name: \_\_\_\_\_  
If the facility is a reference laboratory that will report to its ordering clinician(s), please provide the full name of the laboratory director.  
Otherwise, please provide the full names of the ordering clinicians 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)**

Autofax (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](mailto:RareDiseaseProgram@labcorp.com) or fax to +1-855-224-0888.

Contact Labcorp with any questions regarding account setup through email at [RareDiseaseProgram@labcorp.com](mailto: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 Specialty 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 [privacy@labcorp.com](mailto:privacy@labcorp.com). Labcorp's privacy policy can be found by visiting [www.labcorp.com/about/privacy-information](https://www.labcorp.com/about/privacy-information).

Facility contact signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Required

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## Rare Disease Specialty Testing Program • *Other Countries*

### 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](mailto: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](mailto:rarediseaseprogram@labcorp.com)

## Rare Disease Specialty Testing Program • *Other Countries*

### 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:

- LATAM & Canada  
[\*sangen.mia@marken.com\*](mailto:sangen.mia@marken.com)
- Europe  
[\*sangen.ham@marken.com\*](mailto:sangen.ham@marken.com)
- All other countries email  
[\*sangen.sin@marken.com\*](mailto:sangen.sin@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 (anti-drug antibody, biomarkers, adverse event hypersensitivity, and adverse event neutralizing antibody) and you must complete the appropriate option 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 • *Other Countries*

### 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 includes 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](http://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.

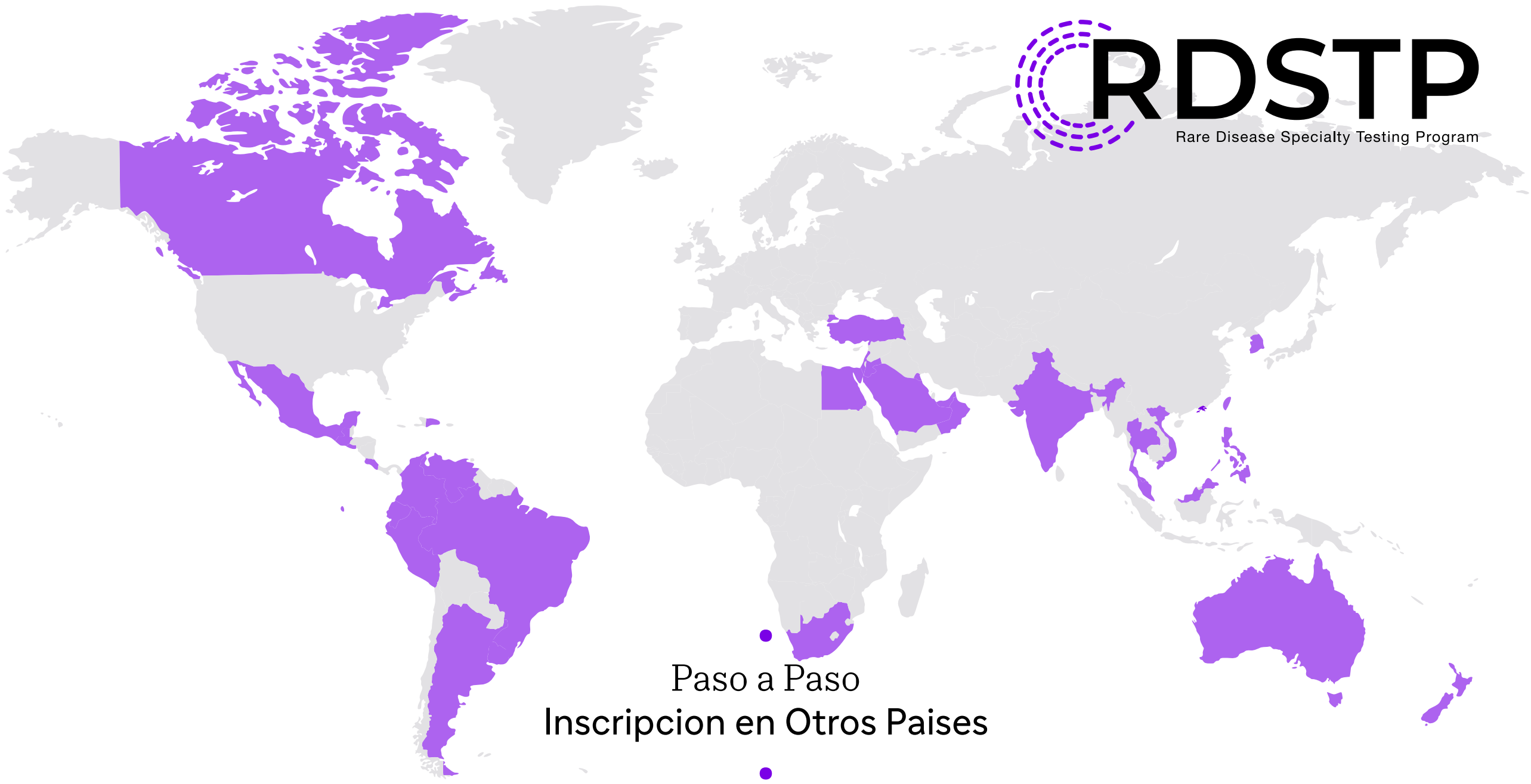
Labcorp offers expedited testing services for all tests, subject to specific conditions. For further details on expediting your test, please contact us at: [\*rarediseaseprogram@labcorp.com\*](mailto:rarediseaseprogram@labcorp.com)

#### *New option*

Alglucosidade alfa IgG Ab testing can be expedited (*5 business days*) for pediatric samples, upon provider request.

For adverse event tests only, (e.g., anti-drug IgE Ab, anti-drug neutralizing Ab), 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 Pharmacovigilance may contact the ordering health care professional for additional adverse event related information. Sanofi does not otherwise receive identifiable result reports from Labcorp.





Paso a Paso  
Inscripcion en Otros Paises

*Listado global detallado  
de otros países del mundo:*

Argentina  
Australia  
Brazil  
Canada  
Colombia  
Costa Rica  
Dominican Republic  
Ecuador  
Egypt  
El Salvador  
Guatemala  
Hong Kong  
India  
Israel  
Jordan  
Kuwait  
Lebanon  
Malaysia  
Mexico  
New Zealand  
Oman  
Peru  
Philipines  
Saudi Arabia  
Singapore  
South Africa  
South Korea  
Taiwan

Thailand  
Turkey  
United Arab Emirates  
Uruguay  
Vietnam  
Venezuela

Si está interesado en inscribirse en nuestro programa, por favor complete los siguientes pasos:

**1.** Paso  
*uno*

Configuración de la  
cuenta de Labcorp

**2.** Paso  
*dos*

Sesión de  
inducción

**3.** Paso  
*tres*

Solicitud de  
pruebas

**4.** Paso  
*cuatro*

Recolección  
de muestras

**5.** Paso  
*cinco*

Entrega de  
resultados

# Rare Disease Specialty Testing Program • Otros países

## Paso 1:

### Configuración de la cuenta de Labcorp

Los profesionales de la salud deben obtener una cuenta de Labcorp específica para el Programa de Pruebas Especializadas en Enfermedades Raras mediante:

- Completar el formulario de configuración de cuenta en línea de Labcorp en: <https://www.labcorp.com/account-setup-international-providers>

o

- Completar el formulario de configuración de cuenta en PDF de Labcorp y enviarlo a: [rarediseaseprogram@labcorp.com](mailto:rarediseaseprogram@labcorp.com)

- Si necesita ayuda para completar el formulario de configuración de cuenta, o requiere asistencia adicional durante el proceso, escriba a: [rarediseaseprogram@labcorp.com](mailto: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)**

Autofax (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](mailto:RareDiseaseProgram@labcorp.com) or fax to +1-855-224-0888.

Contact Labcorp with any questions regarding account setup through email at [RareDiseaseProgram@labcorp.com](mailto: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 [privacy@labcorp.com](mailto:privacy@labcorp.com). Labcorp's privacy policy can be found by visiting [labcorp.com/about/privacy-information](http://labcorp.com/about/privacy-information).

Facility contact signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Required

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## Paso 1:

### *Informacion Adicional*

- El costo de las pruebas y el costo del transporte de las muestras están cubiertos por Sanofi.
- Las muestras pueden ser recolectadas y almacenadas congeladas durante la configuración de la cuenta. Las instituciones pueden obtener las instrucciones de recolección enviando una solicitud a Labcorp a: [rarediseaseprogram@labcorp.com](mailto:rarediseaseprogram@labcorp.com) o los MSL de Sanofi pueden compartir el listado aprobado de pruebas para su país. Labcorp at:  
  
or Sanofi MSLs can share the approved test list flyer for their country.
- Si un laboratorio de referencia es el titular de la cuenta, debe contar con una licencia de exportación válida.
- Si existe una necesidad urgente de acelerar la configuración de la cuenta (por ejemplo, muestras asociadas a eventos adversos), solicite a la institución que envíe el formulario de configuración de cuenta y luego pida el procesamiento acelerado enviando un correo a Labcorp Program Management a: Program Management at:  
[rarediseaseprogram@labcorp.com](mailto:rarediseaseprogram@labcorp.com)

## Paso 2:

### *Sesión de inducción*

Dentro de los *10 a 15 días hábiles* posteriores a la finalización de la configuración de la cuenta, Labcorp enviará información detallada del programa a todas las direcciones de correo electrónico proporcionadas en el Formulario de Configuración de Cuenta, incluyendo:

- Formulario de Solicitud de Pruebas (TRFs).
- Instrucciones para la recolección de muestras.
- Guías para la recolección de muestras.

Después de recibir la información de capacitación por parte de Labcorp, Marken enviará un Starter Pack dentro de 7 a 10 días hábiles. Este paquete contendrá información detallada sobre la recolección de muestras y los servicios de mensajería.

## Información Adicional

### Pasos 2: Capacitación

Todos los documentos de *In-Servicing* se enviarán electrónicamente en formato PDF. El único documento físico que se enviará será el Starter Pack de Marken.

Si una institución aún no ha recibido la capacitación y han pasado más de 10 días hábiles, o si una institución NO ha recibido su Starter Pack de Marken pero sí ha sido capacitada por Labcorp, solicite a la institución que envíe un correo directamente a [rarediseaseprogram@labcorp.com](mailto:rarediseaseprogram@labcorp.com)

Si prefiere contactar a Labcorp en nombre de la institución, asegúrese de copiar también al proveedor o a la institución e incluir suficiente información sobre la cuenta (por ejemplo, nombre de la institución, país, nombre del proveedor).

Para el Starter Pack de Marken, asegúrese de dirigir el correo electrónico al representante de Marken correspondiente:

- LATAM y Canada  
[sangen.mia@marken.com](mailto:sangen.mia@marken.com)
- Europa  
[sangen.ham@marken.com](mailto:sangen.ham@marken.com)
- Todos los demás países  
[sangen.sin@marken.com](mailto:sangen.sin@marken.com)
- También puede copiar sin problema a [rarediseaseprogram@labcorp.com](mailto:rarediseaseprogram@labcorp.com)

### **Paso 3:**

## *Solicitud de Pruebas*

Los profesionales de la salud deben completar el Formulario de Solicitud de Pruebas (TRF) correspondiente para cada paciente.

Tenga en cuenta que, según las pruebas que se soliciten, deberá completar el TRF correspondiente (anticuerpos anti-fármaco, biomarcadores, hipersensibilidad por evento adverso y anticuerpos neutralizantes por evento adverso), seleccionando la opción adecuada para cada paciente.

La información obligatoria que debe incluirse: nombre del paciente, fecha de nacimiento, sexo, nombre del profesional solicitante y prueba solicitada. El tratamiento debe estar indicado cuando se soliciten pruebas de inmunogenicidad.

En la parte superior de cada TRF hay un espacio denominado "send additional copy of report to" donde el profesional puede optar por enviar una copia del resultado a otro proveedor.

Todos los profesionales de la salud pueden utilizar sus propios insumos para la recolección de muestras, siempre que cumplan con los requisitos de Labcorp.

## Paso 4:

### *Recolección de Muestras*

Con un aviso de *2 días hábiles*, Marken retirará las muestras en la fecha y hora solicitadas. Para solicitar el retiro, los profesionales deberán llamar a su oficina local de Marken o enviar por fax/correo electrónico un formulario de reserva completo a la oficina local de Marken.

La institución deberá empaquetar las muestras y los TRF correspondientes (1 paciente por bolsa de riesgo biológico) siguiendo las instrucciones del Starter Pack de Marken, y entregar al conductor una factura completa y la guía aérea en el momento del retiro.

Las muestras serán enviadas a hubs regionales (por ejemplo, Singapur, Hamburgo, Miami) y agrupadas para envíos semanales. Las muestras serán entregadas a Labcorp en Estados Unidos dentro de los *14 días hábiles* posteriores al retiro.

Para pruebas asociadas a eventos adversos, se encuentra disponible el envío acelerado y puede solicitarse al programar el retiro de muestras.

## Paso 4:

### *Información Adicional*

- Los insumos para la recolección de muestras no son proporcionados y deben ser obtenidos por el profesional o la institución de salud (HCP/HCI). Este programa no cubre ni brinda apoyo para los costos de visitas/evaluaciones en consultorio ni para otras pruebas que no estén relacionadas con este programa específico.
- En el momento del retiro, Marken proporcionará todo el material necesario para el transporte de muestras (por ejemplo, bolsas de transporte de 95 kPa, láminas absorbentes, caja de envío, hielo seco).
- Los usuarios deben marcar la opción “adverse event” en el formulario de reserva al coordinar el retiro de muestras, lo que permite que el envío se dirija directamente a los Estados Unidos. Si se solicita el retiro por teléfono, los usuarios deben informar al representante de Marken que el paquete incluye muestras asociadas a eventos adversos.

**Paso 5:**

*Entrega de Resultados*

Los resultados pueden enviarse directamente al profesional de la salud solicitante (HCP) o al laboratorio de referencia por fax o a través del portal en línea de Labcorp ([www.labcorplink.com](http://www.labcorplink.com)).



## Información Adicional

### Paso 5: Entrega de Resultados

Todos los tiempos de procesamiento (TATs) no incluyen el tiempo de transporte de las muestras. Las muestras recogidas fuera de los Estados Unidos pueden demorar hasta **14 días hábiles** en llegar a Labcorp para su análisis.

TATs para pruebas: **14 días hábiles** para pruebas rutinarias, lo que incluye anticuerpos IgG anti-fármaco y biomarcadores.

Las pruebas asociadas a eventos adversos se envían lo antes posible en el siguiente vuelo programado disponible.

Labcorp ofrece servicios acelerados para todas las pruebas, sujetos a condiciones específicas. Para más información sobre cómo acelerar una prueba, comuníquese con: [rarediseaseprogram@labcorp.com](mailto:rarediseaseprogram@labcorp.com)

#### **Nueva opción**

Las pruebas de anticuerpos IgG contra alglucosidasa alfa pueden acelerarse (**5 días hábiles**) para muestras pediátricas, si el profesional lo solicita.

Para pruebas relacionadas únicamente con eventos adversos (por ejemplo, anticuerpos IgE anti-fármaco, anticuerpos neutralizantes anti-fármaco), Labcorp también envía los resultados a Sanofi Global Pharmacovigilance dentro de las **24 horas** posteriores a la finalización del análisis. Si un evento adverso sospechado aún no ha sido reportado para el paciente, Sanofi Pharmacovigilance puede contactar al profesional de la salud solicitante para obtener información adicional relacionada con el evento adverso. Fuera de este proceso, Sanofi no recibe informes de resultados identificables provenientes de Labcorp.

