



Step by Step
United States Enrollment

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&4. Step
*three
& four*

Sample Collection and Submisison

5. Step
five

Results Delivery

Rare Disease Specialty Testing Program • United States

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/setup-information-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

The image shows a screenshot of the 'Rare Disease Specialty Testing Program Account setup form'. The form is titled 'Rare Disease Specialty Testing Program Account setup form' and contains several sections for data entry:

- Facility details:** Fields for Facility name, Facility phone, Facility address (City, ST, County, ZIP), Facility contact name, Facility contact email address, and Laboratory director name.
- Ordering provider(s):** Fields for Name, NPI, and Name for one or more providers.
- Testing (please check the type that may be ordered) (all testing may not be available in all areas):** Radio button options for Anti-Drug IgG Antibody, Adverse Event Hypersensitivity, Adverse Event Neutralizing Antibody, and Biomarkers.
- Labcorp account:** A question 'Are you a current Labcorp client?' with Yes/No options and a field for Labcorp account number if Yes.
- Sample submission details:** A field for 'Samples collected outside of a Labcorp patient service center (if sample pickup address is different than above, please list location details below)'. Below this is a radio button for 'Labcorp patient service center'.
- Results (please select your preferred method for result delivery):** Radio button options for 'Autofax (provide fax number):' and 'Labcorp Link™ online portal (please provide names and email addresses for any Labcorp Link users that require setup)'. Below this is a field for 'Labcorp Link™ online portal (please provide names and email addresses for any Labcorp Link users that require setup)'.

At the bottom of the form, there is a 'Please allow 7-10 business days from receipt of a completed form for account setup. Please send the completed form directly to Labcorp via email to rarediseaseprogram@labcorp.com or fax to 855-24-6885.' section, followed by a 'Contact Labcorp with any questions regarding account setup via email at rarediseaseprogram@labcorp.com.' section. Below that is a certification statement: '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.' This is followed by a privacy policy notice: '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. Labcorp's privacy policy can be found by visiting: <https://www.labcorp.com/our-values/privacy>.' The form ends with 'Facility contact signature: _____ Date: _____' and a 'Required' label. At the very bottom, the Labcorp and Sanofi logos are displayed, along with copyright information: '©2021 Genzyme Corporation. All rights reserved. Sanofi is a registered trademark of Sanofi and Genzyme Corporation. Labcorp is a registered trademark of Labcorp. All rights reserved. 08_27_2019-002'.

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Step 2:

In-Servicing

Within *3 to 5 business days* of the completion of the account setup, Labcorp will provide main account contact with detailed program information such as:

- Test Requisition Form (TRFs).
- Patient service center (PSC) information.
- Sample pickup instructions.

Step 3 and 4:

Sample Collection and Submission

There are two options available for the US:

1. Utilization of one of Labcorp's patient service centers (PSCs) for phlebotomy and transportation services.
- Visit www.Labcorp.com and click on "Make a Lab Appointment" to find the nearest PSC location and schedule an appointment.
 - Patients must attend to their appointment with their completed TRF and a photo ID.
 - 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.
2. Sample collection by the health care professionals outside PSC in compliance with Labcorp's collection requirements and subsequent pickup of samples by Labcorp (call at [1-855-LABCORP](tel:1-855-LABCORP)).
- Within the US, health care professionals can call [855-LABCORP](tel:855-LABCORP) and follow the prompts for ordering supplies.

Step 3 and 4: *Additional Information*

- Please ensure that the sample tube(s) are labeled with two unique patient identifiers that can be matched to the completed TRF(s) along with the sample type (ie, plasma, serum, or urine). Unlabeled or improperly labeled tubes may delay testing and resulting.
- If a specimen collection site was not indicated on the Account Setup Form, and wishes to be added to Labcorp's courier service options, please contact rarediseaseprogram@labcorp.com to add a secondary specimen pickup location.
- When scheduling pickup, please indicate if the pickup will include frozen samples. The sample(s) should be placed in a biohazard bag individually per patient with the completed TRF(s) included in the bag with the sample(s).

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.

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

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

Alglucosidase 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.

