



Rare Disease Gene Panel Program

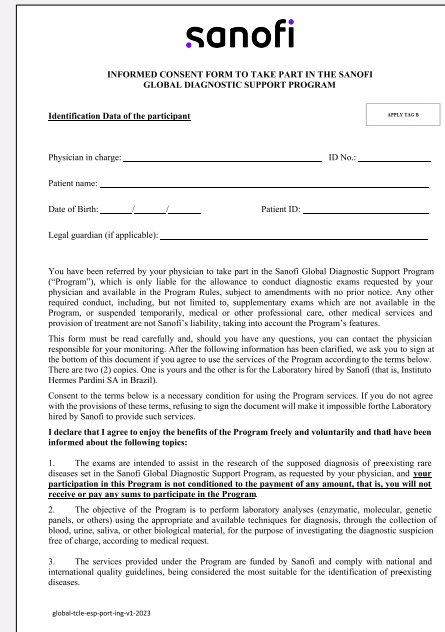
•
Sample collection
and digital submission guidelines
•

Content of the kits received:

1. Collection form



2. ICF
(Consent term)
– 2 copies



The image shows the "INFORMED CONSENT FORM TO TAKE PART IN THE SANOFI GLOBAL DIAGNOSTIC SUPPORT PROGRAM". It includes fields for "Identification Data of the participant" (Name, ID No., Date of Birth, Patient ID, Legal guardian) and a section for "Consent to the terms below". The form also contains a declaration of agreement and a list of three points regarding the program's objectives and funding. The Sanofi logo is at the top.

3. Plastic envelope for return



Content of the kits received:

4. Silica gel bag



5. External envelope



6. Informative flyer

RDGenePP Advancing Genetic Diagnostics in Partnership with Sanofi

Welcome to the RDGenePP, a global diagnostic program sponsored by Sanofi with the main purpose of shortening rare disease patients' diagnostic journey.

At Sanofi, we recognize the impact of genetic diseases on patients' and their relatives' lives. This recognition fuels our dedication to collaborating with key laboratory partners for genetic analysis and with TBTB Global to handle sample processing and program management, ensuring a streamlined and efficient process.

Explore the Top Features of the RDGenePP App

- In-App Support Chat**
- Supporting Guides**
- Push Notifications**
- Visual Analytics**
- Intuitive Sample Submission**
- Live Sample Tracking**

Step-by-Step Sample Submission with RDGenePP App

- Account Creation**
Create or log into your account.
- Physician Statement**
A digital signature for Program's Physician Statement will be required.
- Test Request Form & Informed Consent**
Accurately fill in the Test Request Form with patient details. Upload the patient-signed Informed Consent.
- Digital Signature Utilization**
Use the app's digital signature feature to securely sign all required documents within the app before submission, including physician statement.
- Arrange for Pickup**
Request a pickup through the app if needed for your sample.
- Secure Your Submission**
Save the submission in the app to track and manage it effectively.
- Assistance and Results**
Engage with the support team via chat for help and stay alert for results.

rdgbbiade.com/rdgenepp_app

Scan QR and Start Your Journey to Health Insights with RDGenePP App

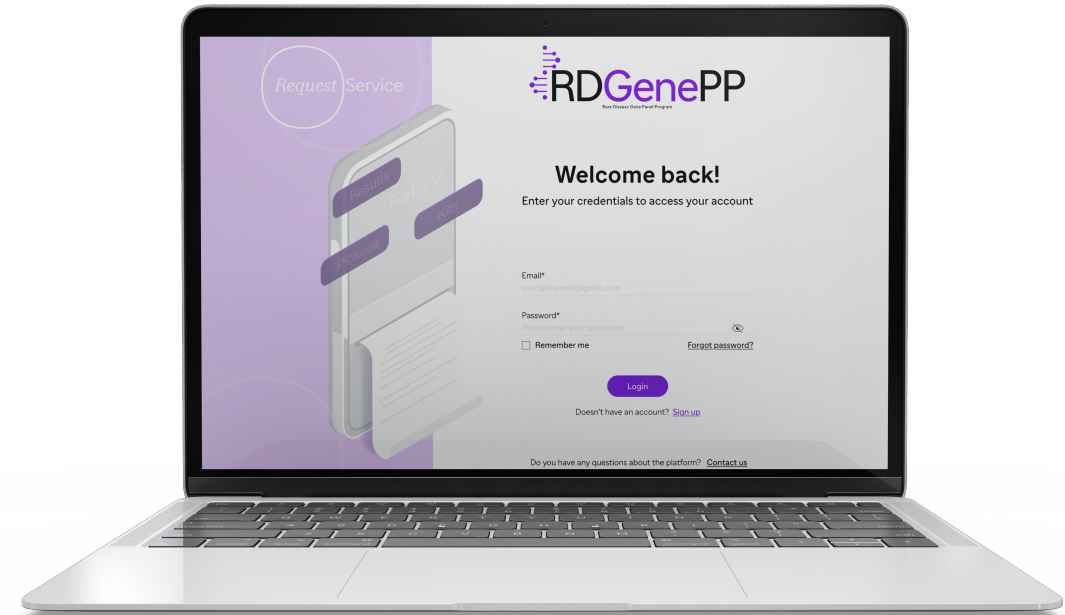
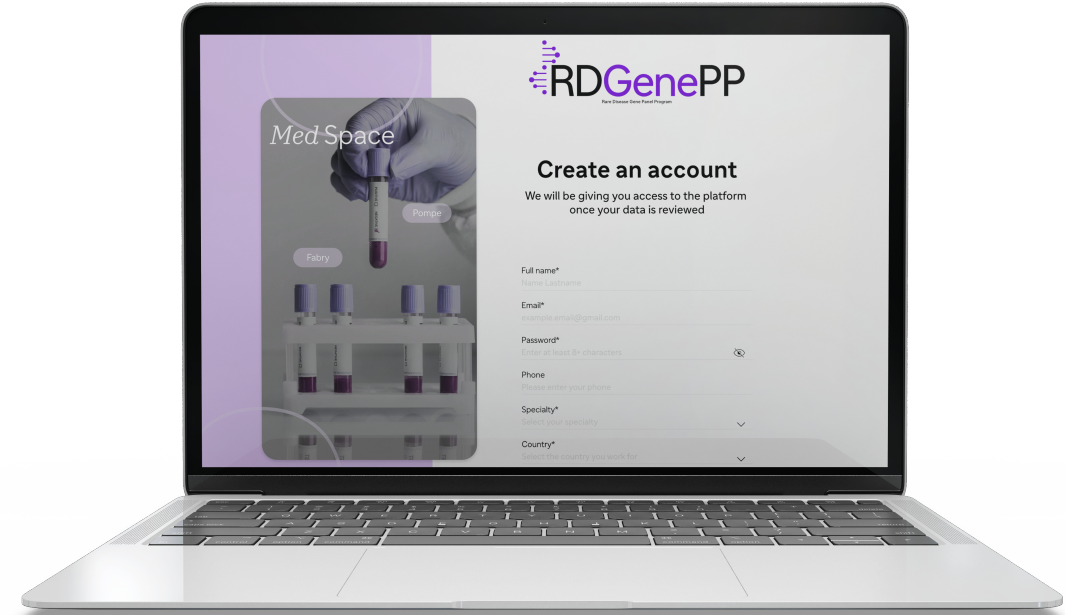
Step 1:

Log in and Fill the Test Request Form within the App

Rare Disease Gene Panel Program

Section A: *Login*

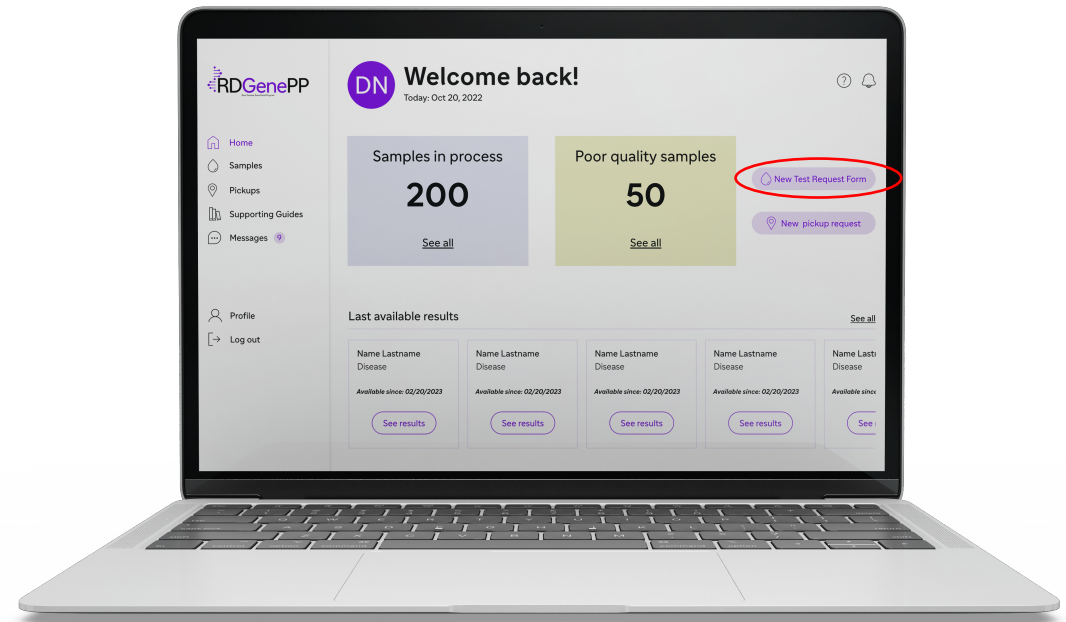
- Please log in to your account within the app.
- If you are not yet registered, proceed and complete the registration process.
- You will need to sign the Physician Statement when you are filling out your first request. It will be saved in your profile for future requests.



Rare Disease Gene Panel Program

Section B: *Selection of Test Request Options*

- Click on the “New Test Request Form” tab.
- Select “New Sample Registration” to enter sample details.
- Double-check all details for accuracy before submitting.

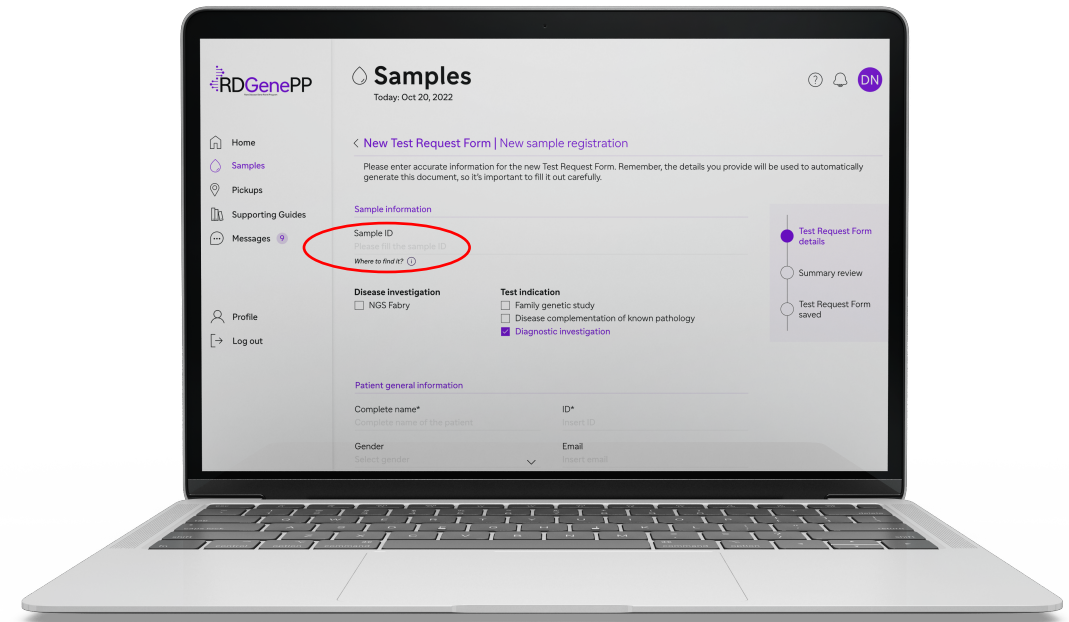


Rare Disease Gene Panel Program

Section C:

Test Request and Sample ID Entry

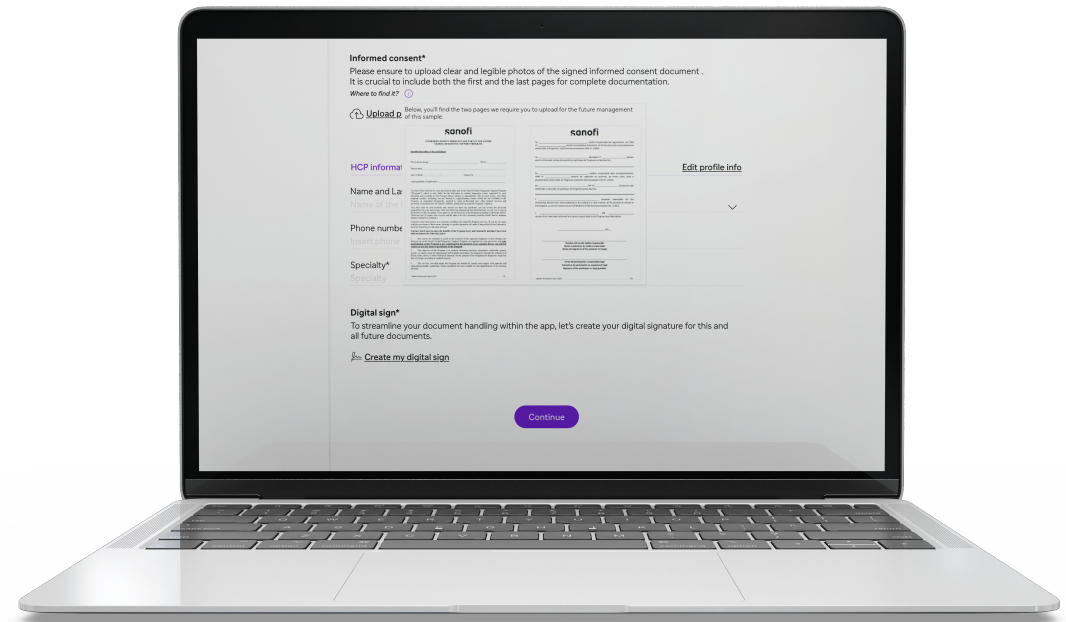
- Fill in the Test Request Form with the patient's full information.
- If the sample is being collected by an HCP, enter the Sample ID that matches the physical form.
- If the sample is being collected by a local reference center, leave the Sample ID field blank.
- Please ensure all details are precise to guarantee the accuracy of the test records.



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Section D: *Informed Consent Documentation*

- Upload the patient's signed Informed Consent form, ensuring the photos are clear and legible.
- Follow the on-screen details for specific pages required for the upload.
- Confirm the visibility of all text and signatures prior to submission.



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Section D: ICF Additional Information

Fill with Patient Information



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INFORMED CONSENT FORM TO TAKE PART IN THE SANOFI
GLOBAL DIAGNOSTIC SUPPORT PROGRAM

Identification Data of the participant APPLY TAG B

Physician in charge: _____ ID No.: _____

Patient name: _____

Date of Birth: ____/____/____ Patient ID: _____

Legal guardian (if applicable): _____

You have been referred by your physician to take part in the Sanofi Global Diagnostic Support Program ("Program"), which is only liable for the allowance to conduct diagnostic exams requested by your physician and available in the Program Rules, subject to amendments with no prior notice. Any other required conduct, including, but not limited to, supplementary exams which are not available in the Program, or suspended temporarily, medical or other professional care, other medical services and provision of treatment are not Sanofi's liability, taking into account the Program's features.

This form must be read carefully and, should you have any questions, you can contact the physician responsible for your monitoring. After the following information has been clarified, we ask you to sign at the bottom of this document if you agree to use the services of the Program according to the terms below. There are two (2) copies. One is yours and the other is for the Laboratory hired by Sanofi (that is, Instituto Hermes Pardini SA in Brazil).

Consent to the terms below is a necessary condition for using the Program services. If you do not agree with the provisions of these terms, refusing to sign the document will make it impossible for the Laboratory hired by Sanofi to provide such services.

I declare that I agree to enjoy the benefits of the Program freely and voluntarily and that have been informed about the following topics:

1. The exams are intended to assist in the research of the supposed diagnosis of preexisting rare diseases set in the Sanofi Global Diagnostic Support Program, as requested by your physician, and **your participation in this Program is not conditioned to the payment of any amount, that is, you will not receive or pay any sums to participate in the Program**
2. The objective of the Program is to perform laboratory analyses (enzymatic, molecular, genetic panels, or others) using the appropriate and available techniques for diagnosis, through the collection of blood, urine, saliva, or other biological material, for the purpose of investigating the diagnostic suspicion free of charge, according to medical request.
3. The services provided under the Program are funded by Sanofi and comply with national and international quality guidelines, being considered the most suitable for the identification of preexisting diseases.

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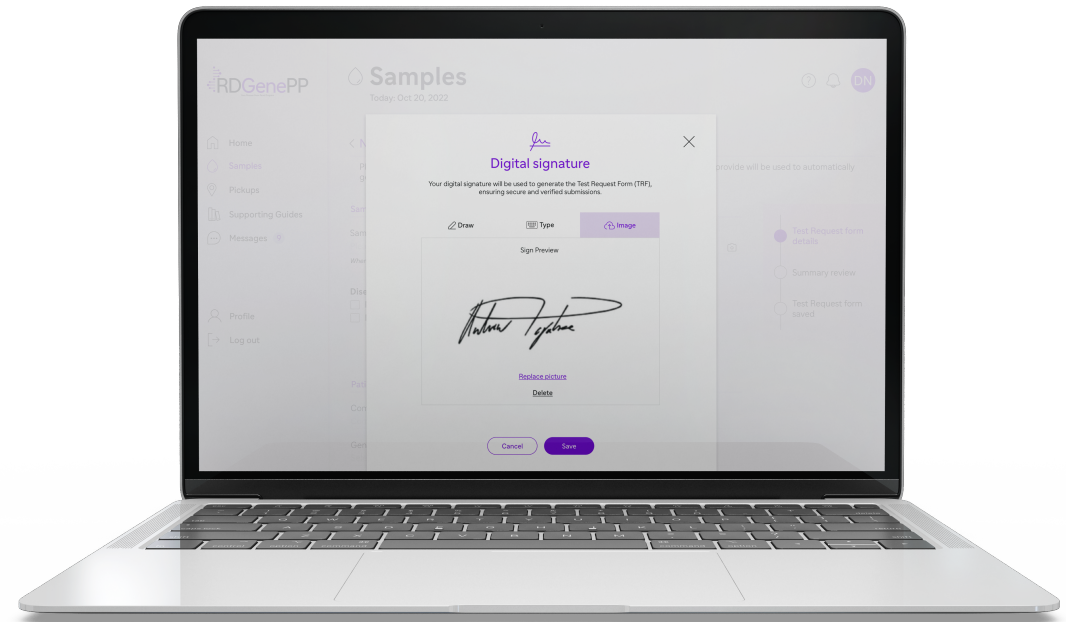
← Apply Tag A

- ⚠ Patient or guardian signature on last page. **(mandatory)**
- ⚠ Upload an image of the signed ICF to the corresponding section on the sample request within the app.

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Section E: *Digital Signature*

- Use the “Digital Signature” feature to sign the document electronically.
- Check that the signature is correctly captured and proceed to save it in the system.



Step 2: Sample Collection Process

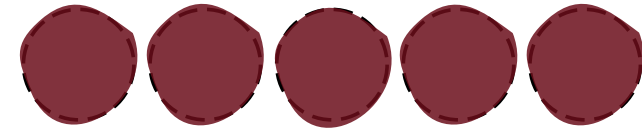
Rare Disease Gene Panel Program

Step 2:

Tips for Successful Sample Collection

- Sufficient and homogeneous concentration of sample.
- Blood should be viewed in both sides of the filter.
- Sample could be drawn with needle or by capillary puncture.
- Important to fill all the paper filter circle with the blood.
- If the sample doesn't meet the quality standard, a new sample collection will be asked.

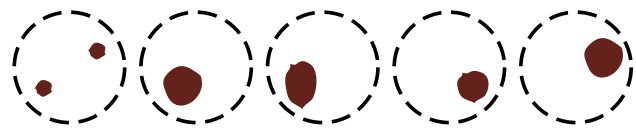
Successful sample



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Step 2:
Wrong Collection

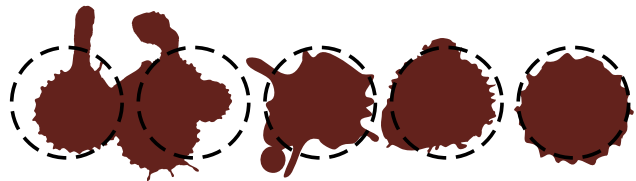
Insufficient sample



Supersaturated sample



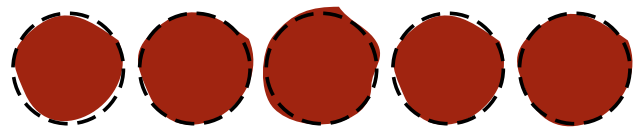
Overlapped sample



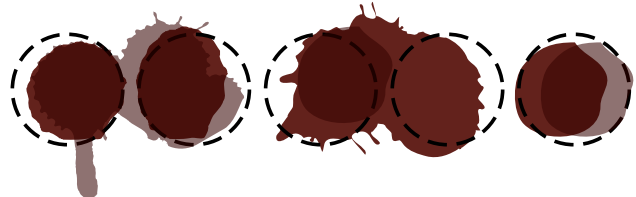
Diluted sample



Wet sample



Coagulated sample



Rare Disease Gene Panel Program

Step 2: Additional Information

Preencha com letra de forma - Não rasure - Usar alfabeto latino | Capital letters only - Do not rip - Use latin alphabet | Le

Paciente / Patient

Gênero / Gender / Género M F _____ DN / DOB / FN D D M M Y Y Y Y Y Telefone / Phone / Teléfono

E-mail / Correo Electrónico

Médico / Physician

Telefone / Phone / Teléfono Celular / Ce **Collect the sample following the instructions on the kit.**

E-mail / Correo Electrónico

Instituição / Institution / Institución

Telefone / Phone / Teléfono Celular / Cell Phone / Teléfono Móvil País / Country

E-mail / Correo Electrónico

INSTRUÇÕES / INSTRUCTIONS / INSTRUCCIONES

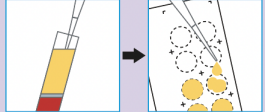
- Realize a coleta seguindo as instruções ao lado para cada tipo de amostra.
- Assinale o tipo de amostra.
- Cole a etiqueta A no papel filtro e a etiqueta B na solicitação do exame.
- Deixe secar naturalmente, em superfície limpa, plana, horizontal e seca, por pelo menos 3 horas.
- Nunca utilizar meios para acelerar a secagem (estufa, sol, secador de cabelo, microondas etc.).
- Concluída a secagem, coloque a amostra no envelope do formulário, sele e coloque dentro do envelope plástico de proteção.
- Mantenha em temperatura ambiente (18°C a 25°C) até o envio ao Laboratório DLE.

- Perform the collection by following the instructions for each sample on the right.
- Check the type of sample collected.
- Paste the tag A on the filter paper end the tag B on the test request form.
- Let it drying naturally, in a clean, horizontal and polished area, for at least 3 hours.
- Never use ways to accelerate drying (stove, sun, hair dryer, microwave, fan etc.).
- After the drying is completed, place the sample into the envelope form, seal and insert into protection plastic envelope.
- Keep it in room temperature (18°C to 25°C) until shipping to DLE Laboratory.

- Realice la recolección siguiendo las instrucciones al lado, para cada tipo de muestra.
- Marque el tipo de muestra recolectada y .
- Pegue la etiqueta A en el papel de filtro y la etiqueta B en el Formulario de solicitud.
- Deje secar naturalmente, en superficie limpia, lisa, plana y seca, durante al menos 3 horas.
- Nunca utilizar medios que aceleren el secado (estufa, sol, secador de pelo, microondas, etc.).
- Terminado el secado, deposite la muestra y selle el formulario, y después guárdelo en el sobre plástico.
- Mantenga en temperatura ambiente (18°C a 25°C) hasta el envío al Laboratorio DLE.

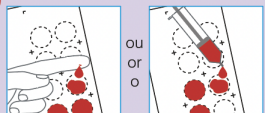
dle.com.br

Plasma Heparinizado / Heparinized Plasma Plasma con Heparina



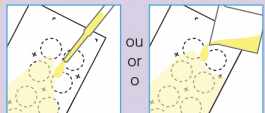
Preencha completamente os círculos.
Fill all circles completely.
Llene completamente todos los círculos.

Sangue / Blood / Sangre



Preencha completamente os círculos.
Fill all circles completely.
Llene completamente todos los círculos.

Urina / Urine / Orina



Preencher completamente o papel filtro.
Fill the filter paper completely.
Llenar completamente el papel filtro.

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Step 3: Sample Packaging and Submission

Rare Disease Gene Panel Program

Step 3: Completing Collection Form

Fill out the physical Collection Form that accompanies the sample, ensuring all sections are complete:

A) Patient information

Use capital letters. Do not abbreviate.

B) Clinic/Physician Information

Important: Be careful in writing the e-mail with readable letter to ensure receipt of results.

C) Select Test.

D) Inform Sample Collect Sample.

E) Protocol

The physician should keep the protocol to guarantee the traceability of sample via barcode.

The image displays the 'Collection Form' and 'Collection Card' for the Rare Disease Gene Panel Program. The form is divided into sections for patient information (A), clinic/physician information (B), test selection (C), sample collection information (D), and protocol (E). The collection card includes a barcode, a signature line, and a warning not to touch the filter paper.

Preencha com letra de forma - Não rasure - Usar alfabeto latino | Capital letters only - Do not rip - Use latin alphabet | Letras de molde - No borre - Utilizar el alfabeto latino

Paciente / Patient
Gênero / Gender / Género: M F **A** Telefone / Phone / Teléfono: **A**
E-mail / Correo Electrónico: **A**

Médico / Physician
Telefone / Phone / Teléfono: **B** Phone / Teléfono Móvil: **B** País / Country: **B**
E-mail / Correo Electrónico: **B**

Instituição / Institution / Institución
Telefone / Phone / Teléfono: **B** Phone / Teléfono Móvil: **B** País / Country: **B**
E-mail / Correo Electrónico: **B**

Doença investigada / Disease investigation / Enfermedad investigada
 POMPE MADD / GALTURIGER MPS I FABRY **C**
 1ª amostra / 1st **C**
 Recoleta / recolecta / recollido **C**

Tipo de investigação / Type of investigation / Tipo de investigación
(Assinalar apenas uma opção / Check just one option / Marque sólo una opción)
 PACIENTE ÍNDICE / INDEX PATIENT / PACIENTE INDEX **D**
 TRAGEM FAMILIAR / FAMILY SCREENING / ESTUDIO FAMILIAR **D**
Mutação de caso índice / Mutación del caso índice: **D**
Grau de parentesco / Grado de parentesco: **D**

Protocolo
Data coleta / Collection date / Fecha de recolección: **E**
Requerente sem / Examen solicitado: **E**

CARTÃO DE COLETA / COLLECTION CARD / TARIETA DE COLECCION
Paciente / Patient: **E**
Data coleta / Collection date / Fecha de recolección: **E**
Tipo de amostra / Sample / Tipo de muestra:
 Plasma Heparinizado Sangue Urina
 Plasma Heparinizado Plasma com Heparina Sangue Urina

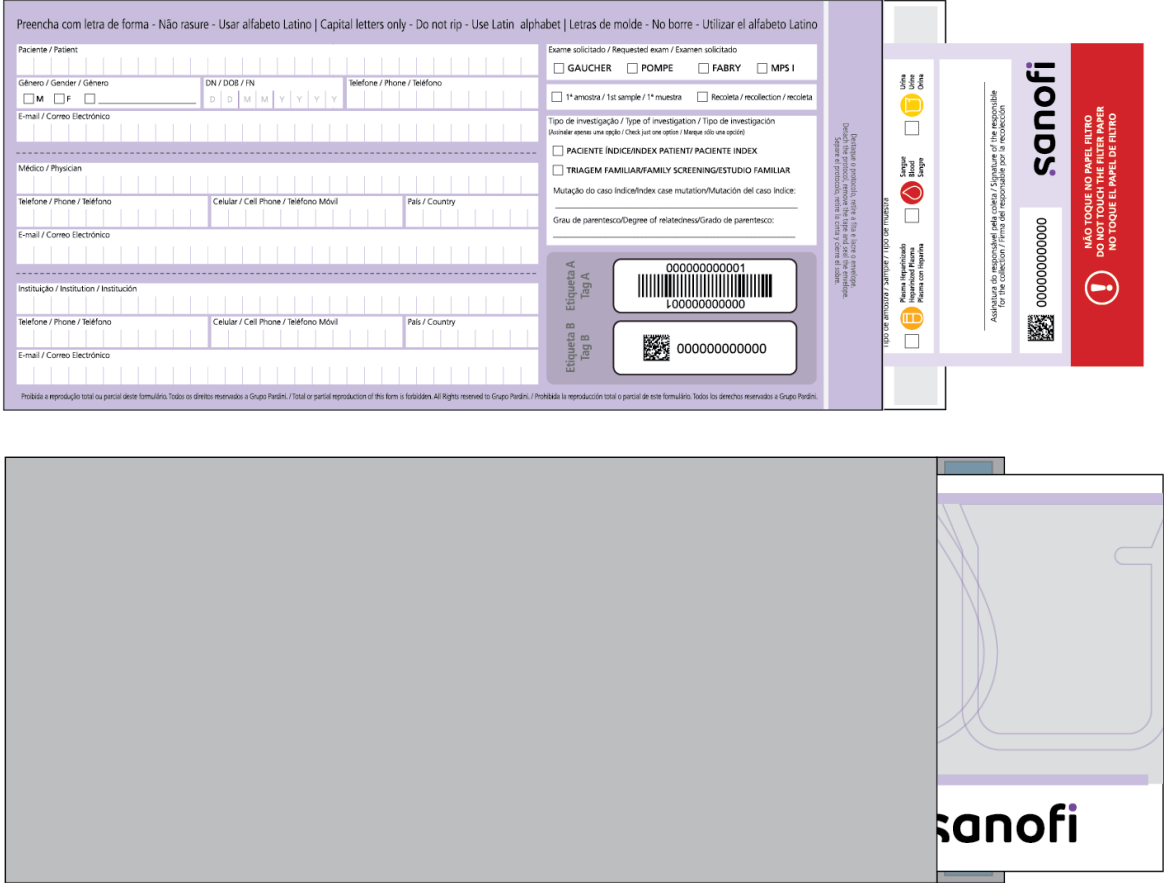
Assinatura do responsável pela coleta / Signature of the responsible for the collection / Firma del responsable por la recolección: **E**

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NÃO TOQUE NO PAPEL FILTRO / DO NOT TOUCH THE FILTER PAPER / NO TOQUE EL PAPEL DE FILTRO

Rare Disease Gene Panel Program

Step 3: Correct placement



Place the dried blood spot card into the form envelope and seal it.

Insert the form envelope inside the plastic bag with silica gel and seal it.

The logo for the Rare Disease Gene Panel Program (RD Gene PP) features a stylized DNA double helix on the left, composed of purple dots and lines. To the right of the graphic, the text "RD Gene PP" is displayed in a bold, sans-serif font. "RD" and "PP" are in black, while "Gene" is in purple.

RD Gene PP

Rare Disease Gene Panel Program