

INTENDED USE OF THE KIT

This kit is specifically designed for the collection and preservation of peripheral blood samples obtained by venipuncture and saliva samples and their subsequent shipment to Juno Genetics España laboratories at room temperature.

KIT CONTENTS (Provided kit depends on the sample requested to be collected)

Peripheral blood samples



EDTA collection tube
(Lavender coloured cap)



Protective plastic case with absorbent material



Test Request Form (TRF)

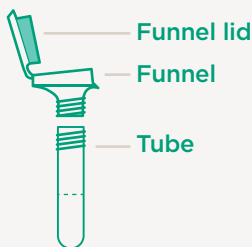


Informed consent form



Envelope for kit shipment

Saliva samples



Small cap for tube



Sponge*



Test Request Form (TRF)



Informed consent form



Envelope for kit shipment

*Available on selected kits when donors are children or donors who cannot spit.

INSTRUCTIONS PRIOR TO SAMPLE COLLECTION

A Preparation of the patient. Pre-checks to be carried out on the patient.

For blood sample:

No specific preparation of the patient is necessary for blood collection. However, it is recommended that the section "SPECIFIC CONSIDERATIONS TO BE TAKEN INTO ACCOUNT THAT MAY COMPROMISE TEST RESULTS" be reviewed beforehand.

In the event that for any reason it is not possible to obtain a blood sample (e.g. infant population, adults with difficulty for blood collection) you can request alternative kits for these cases. Contact the laboratory to discuss the options available.

For saliva sample:

Read the kit instructions.

B Checks to be made on the material supplied.

Common elements to review for all kits

- Check that the kit contains all the indicated elements before proceeding with the sample collection.
- Store the kit at a temperature at room temperature until use. Check kit info for optimal temp storage.
- Check the expiry date of the tube. Discard it if it is possible that the expiry date will have passed by the time it arrives at the laboratory.

Specifically for blood kit

- Regarding the blood tube supplied:
 - Check that it is an EDTA tube (lavender, purple or lilac cap).
- Regarding the case with protective absorbent pad:
 - Check the integrity of the case. Check for any breakage.
 - Confirm that it remains closed once the tube has been inserted.

Specifically for saliva kit

- Read the kit instructions.
- Firmly attach the saliva tube within the plastic case and check that remain closed.

C Amount of sample to be collected.

Blood: It is recommended to collect 5ml.

Saliva: collect saliva until filling the line indicated in the instructions.

D How to properly label the sample.

Label the tube or kit with at least NAME + FIRST SURNAME of the patient and DATE OF BIRTH in numerical format (DD/MM/YYYYY). It is possible to indicate the initials instead of complete name when space is limited.

E Criteria for acceptance and rejection of the sample by the laboratory.

Please note that the following elements may result in the rejection of the sample:

- The sample is not accompanied by the appropriate documentation: Application form and informed consent.
- Errors in the information contained in the documentation, e.g.:
 - Mandatory fields not filled in. The mandatory fields are indicated on the application form.
 - Documents not signed by the doctor or patient.
- Errors in the labelling of the primary packaging containing the sample, e.g.:
 - The patient's identification data does not fully match the information on the submitted documentation.
- Regarding the samples, e.g.:
 - The expiry date on the tube or kit has been exceeded by the time it arrives at the laboratory.
 - A different blood collection tube or kit to the one supplied by the laboratory is used.
 - The sample shows evidence of having undergone heat stress situations, e.g. freezing or high temperatures.
 - More than 3 days have elapsed between delivery to the transport company and receipt of the sample in the laboratory.

F Expected time for delivery of results.

The maximum deadline for the assessment of the case acceptance is 30 working days, counting from the moment that all requested samples have arrived along with its associated documentation at the JUNO GENETICS laboratory.

Please take this into account when scheduling any medical appointments related to the results offered by this test.

**When you receive the kit, it is important to check
that the collection tube or kit has not expired.**

Store the kit at room temperature

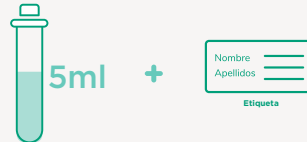
INSTRUCTIONS DURING SAMPLE COLLECTION:

The sample should be collected by a healthcare professional, using the tube provided by Juno Genetics. If there are any problems with the tube or collection kit, please contact Juno Genetics.

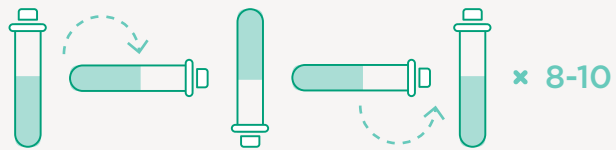
A1

Steps for blood sample collection.

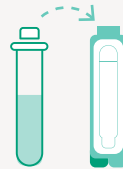
Draw 5ml of blood in a 10ml tube with EDTA and label with the patient's name and 5ml date of birth.



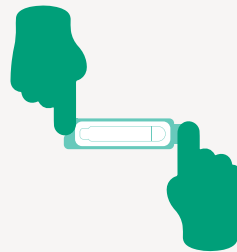
Mix carefully 8-10 times. Do not shake the tube.



Insert the blood tube into the pre-moulded shapes in the protective case to hold them in place. First make sure that the tube is tightly closed and no leaks are observed.



Close the case and press firmly along the edges of the case.



Add the date of blood collection to the pre-completed Test Request Form (TRF).



A2

Steps for saliva sample collection.

Follow the kit instructions.

B

Stabilisation and storage of the sample.

Send the sample as soon as possible after collection. It is recommended that it be sent on the day of collection.

If blood sample cannot be sent immediately after collection, it is recommended to be stored in a refrigerator between 4°C and 8°C for a maximum of 7 days. After this period, it is recommended to discard the blood and collect a new blood sample.

For saliva sample follow the kit instructions.

The sample should NEVER be stored in the freezer. This can degrade the sample.

INSTRUCTIONS FOR TRANSPORTING THE SAMPLE:

A

Packaging and labelling of the sample for transport.

Place the tube or collection kit in its container and the request form in the kit sent by Juno. It is important that the tube container fits securely into the kit box.



Place the kit in the envelope that came with the kit. Attach the return label, which will be sent to you once the collection has been arranged with DHL.



It is important NOT to cover any of the images/text on the packaging (especially the phrase: EXEMPT HUMAN SPECIMEN).

B

Specific requirements for shipping times during transport.

It is recommended that the sample should not take more than 3 days from delivery to the transport company until it arrives at the laboratory. Please take into account possible holiday periods when planning the blood collection and shipment of the sample.

C

Specific requirements for storage conditions during transport (temperature and/or preservatives).

Samples can be shipped at room temperature, requiring no special means of temperature control during transport.

If the ambient temperature is higher than 35°C, it is recommended to send the samples with cold accumulators. If this occurs, it is recommended to contact the laboratory beforehand.

D

Information for sample collection/delivery by courier company.

It is important to note that biological samples cannot be delivered to local DHL offices.

To arrange for a courier to collect the sample from your home please contact Juno Genetics customer service at least 24 hours prior to collection by email at supportspain@junogenetics.com indicating the collection address.

You can also contact us by phone on: **+34 96 069 48 00.**

SPECIFIC CONSIDERATIONS TO TAKE INTO ACCOUNT THAT MAY COMPROMISE THE TEST RESULTS

- In the event that you need to use a different blood tube or collection kit to the one supplied, please note that this may compromise the viability of the test. Only use blood tubes with EDTA as an additive. Other preservatives used may affect the test result.
- Please note that it is VERY IMPORTANT that you do not perform this test if:
 - You have recently received a blood transfusion (less than 60 days).
 - You are a bone marrow transplant recipient.
- In these cases, it is necessary to obtain a non-blood sample. Ask for an alternative kit to test these cases.

WARNINGS AND PRECAUTIONS

Saliva collection kit:

See kit instructions

BASIC LABORATORY CONTACT DETAILS

Contact email:

supportspain@junogenetics.com

Telephone:

(+34) 96 069 48 00

Address:

Juno Genetics España

Ronda Guglielmo Marconi, 11-A,

1º22B 46980-Paterna, Valencia, Spain

www.junogenetics.es

Thank you
for choosing Juno Genetics