

INTENDED USE OF THE KIT

This kit is specifically designed for the collection, preservation, and shipment of peripheral blood samples to Juno Genetics España. The blood samples should be obtained by venipuncture by healthcare personnel and shipped at room temperature.

CONTENTS OF THE KIT



EDTA blood tube with
patient's details
(Lavender coloured cap)



Protective plastic case with
absorbent material.



Test request
form (*)



Informed
consent (**)



Envelope for
sending the kit

(*) Only in case of Carrier (**) Only in case of prePGT

INSTRUCTIONS PRIOR TO SAMPLE COLLECTION

A Patient preparation. Preliminary checks to be carried out on the patient.

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.

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

B Checks to be carried out on the material provided.

- Check that the kit contains all the indicated items before proceeding with the blood draw.
- Store the kit at a temperature between 4°C and 25°C until use.
- Regarding the tube provided for blood draw.
 - Check the expiry date of the blood tube. Discard it if it is likely to be out of date by the time it arrives to the laboratory.
 - Check that it is an EDTA tube (lavender, purple or lilac coloured cap).
- Regarding the plastic case with absorbent material:
 - Check the integrity of the case. Check for cracks.
 - Confirm that it remains closed once the tube has been inserted.

C Quantity of sample to be collected.

The engraved 360° minimum fill indicator on the tube represents the minimum volume of blood required for proper analysis. Check that the blood level is at or above the lower edge of the minimum fill indicator.

D How to correctly label the sample.

If the tube is not labelled, label the blood sample tube with the following information: NAME + FIRST SURNAME of the patient and DATE OF BIRTH in numerical format (DD/MM/YYYY).

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

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

- The sample is not accompanied by the appropriate documentation: test request form and/or informed consent.
- Errors in the information contained in the documentation, for example:
 - Mandatory fields not filled in. Mandatory fields are indicated in the test request form.
 - Documents not signed by the doctor or the patient.
- Errors in the labelling of the primary packaging containing the sample, for example:
 - The patient's identification data does not fully coincide with the information in the documentation submitted.
- Issues with the blood sample tube, such as:
 - The expiry date of the kit has been exceeded when it arrives at the laboratory.
 - A different blood collection tube than the one supplied by the laboratory is used.
 - The sample shows evidence of heat stress, e.g. freezing or high temperatures.

F Deadline for delivery of results.

The turnaround time for results will depend on the test requested. For specific timeframes for your test, please consult your doctor.

Delivery times for results are counted from the moment the blood sample arrives at the JUNO GENETICS laboratory, together with the documentation associated with the test. Please take this into account when scheduling any medical appointments.

**When receiving the kit, it is important to check that the tube for collecting blood has not expired.
Store the kit between 4°C and 25°C before use.**

INSTRUCTIONS FOR BLOOD DRAW:

The sample should be collected by a healthcare professional, using the tube provided by Juno Genetics. In case of any problems with the tube, please contact Juno Genetics.

A

Steps to obtain the sample.

Draw blood into the EDTA tube labelled with the patient's data. In case of any problems with the tube, use an EDTA blood tube and label it with the patient's name and date of birth (see **WARNINGS AND PRECAUTIONS** section).



Invert about 8-10 times. Do not shake. Vigorous mixing may cause foaming or haemolysis. Inadequate mixing may cause platelet clumping, clotting and incorrect analytical results.



Insert the blood tube into the provided protective plastic case to hold it 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 on the pre-filled test request form (TRF) the date of blood collection (Carrier test only).



B

Stabilisation and storage of the sample.

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

If it cannot be shipped immediately after extraction, it is recommended that it 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.

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

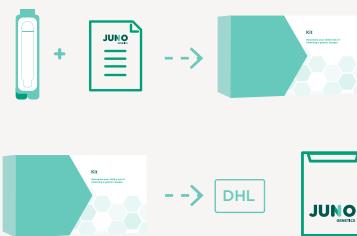
INSTRUCTIONS FOR THE TRANSPORT OF THE SAMPLE:

A

Packaging and labelling of the sample for transport.

Place the tube in its case and the test request form in the kit sent by Juno. It is important that the case fits snugly into the slots available inside the kit box.

Insert the kit in the kit shipping envelope and attach the return label to the outside of the envelope. This label will be sent to you once collection has been arranged with DHL.



**Important. DO NOT cover any of the images/texts on the envelope for the sending of the kit.
Especially not to cover the phrase: EXEMPT HUMAN SPECIMEN**

B

Specific requirements on shipping times during transport.

Please take into account possible holiday periods when planning the blood collection and shipment of the sample; it is recommended that the sample takes no more than 3 days from delivery to the transport company until it arrives at the laboratory.

C

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

Samples can be shipped at room temperature, without the need for special means of temperature control during transport.

D

Information for sample collection/delivery by transport company.

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

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

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

SPECIFIC CONSIDERATIONS TO BE TAKEN INTO ACCOUNT THAT MAY COMPROMISE TEST RESULTS

- Please note that it is VERY IMPORTANT that you do not take this test if:
 - You have recently received a blood transfusion (less than 60 days).
 - You are a bone marrow transplant recipient.
- For the above cases it is necessary to obtain a non-blood sample.
Please ask JUNO GENETICS for an alternative kit to perform the test in such cases.

WARNINGS AND PRECAUTIONS

If the healthcare professional is unable to use the blood collection tube provided, they should consult JUNO GENETICS to ensure that the tubes to be used instead are adequate to ensure proper functioning of the test.

BASIC LABORATORY CONTACT DETAILS

Email contact:

supportspain@junogenetics.com

Telephone:

(+34) 96 069 48 00.

Address:

Juno Genetics Spain

Ronda Guglielmo Marconi, 11-A, 1º22B

46980-Paterna, Valencia, Spain

www.junogenetics.eu

We thank you
for choosing Juno Genetics.

JUNO
GENETICS