

Sample collection and sending samples for Harmony NIPT, performed in Sweden.

1. Electronic referral.

We prefer that the electronic system for referrals and reporting is used.

Log in to

<https://login.sv.fostertest.se/Account/Login.aspx>

Fill in patient information. Save. Print the referral including consent. Both the patient and the clinician must sign the referral. Put the referral along with the blood sample tubes in the sampling kit.

When the report is ready, e-mail will be sent automatically. Log in to the electronic system and download the report. If there is a high-risk result, you will also be contacted by e-mail.

Reporting time is currently normally 4-9 working days.

2. Paper Referral

There is the possibility to use paper referrals.

3. Take blood sample

Take 2 tubes of peripheral venous blood (whole blood) from the pregnant woman in cell-free DNA, Roche tubes (8.5 ml, vacuum tubes, Cell-Free DNA Collection Tube, Ref.no. 07785666001). Gently mix the blood by inverting it a few times. Store the blood at room temperature (6-35 ° C).

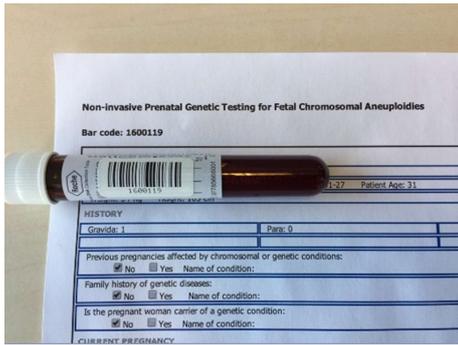
There are no specific pre-analytical requirements for the patient.

Write the patient's name and birth date on the tubes, check that the referral ID and bar codes on the tubes are correct. Determine the identity of the patient with identification. (At least one fully filled tube or 3 half-filled tubes are needed for the analysis to be performed.)

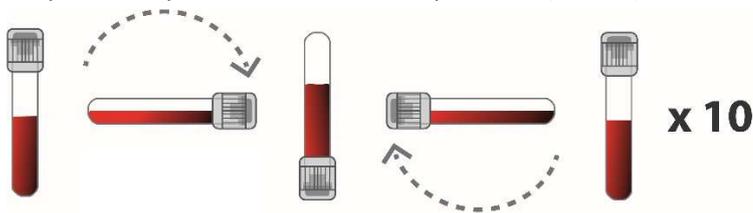
Take care of infectious, cutting waste according to local routines.

Fill out the referral form, save and print it out. The patient should read the information and sign the form. The patient should receive information about the test, how data is evaluated, about the medical report and limitations of the test before signing the form. The Doctor should also sign the referral.

Adhesive labels with barcodes in triplicate are provided from Life Genomics. Find the corresponding labels and put them on the two sample tubes for cell-free DNA, Roche (8,5 ml, vacuum-tubes).



Disinfect the area for blood withdrawal. Withdraw blood (peripheral venous blood, whole blood) into the two sample tubes for cell-free DNA, Roche (8,5 ml, vacuum-tubes). Mix the blood **carefully** through gently inverting the tubes 10 times (see figure 2). Keep the sample tubes at room temperature (6-35°C).



4. To pack the blood sample

Put the tubes back in the sampling kit as they come, together with the signed referral form. Place the sampling kit in an envelope. Several kits can be placed in the same envelope. Place the shipping note on the envelope. Seal tightly with tape.

5. Transporting blood samples to Life Genomics

Preferably send the samples the same day they are taken. Avoid sending samples on Fridays - store the samples at room temperature over the weekend and send them on Monday. The samples are stable for 7 days at room temperature. Send the tracking number to Life Genomics either via the e-referral or e-mail to info@lifegenomics.se

6. Book transportation using DHL.

Use DHL to send samples to Life Genomics. Samples should be sent as "Exempt human specimen". (Not UN3373.) Life Genomics can supply adhesive stickers with "Exempt human specimen". Ask DHL for envelopes. Use Life Genomics DHL account for the charges. Life Genomics DHL account number: 961999520

Life Genomics
 Att: Eva Arkblad
 Odinsgatan 28
 411 03 Göteborg
 Tel: +46-708-58 33 72

NOTE you have to be available for DHL to pick up the package after the booking is made.



The following is provided by Life Genomics:

Sampling kit with 2 Roche cell-free DNA tubes (plastic).

Patient information and brochures.

Login information to electronic system for referral and reporting.

Life Genomics is open weekdays 8-16 pm but often answer the phone outside these times.

In order to accept blood samples for analysis with Harmony NIPT, the samples need to be labeled with ID and accompanied by either electronic or paper referrals and arrive at the laboratory within 7 days from the sampling. If samples do not meet the requirements for being accepted we will contact you.

Hemolysis results in a reduction of the fetal fraction and in case of highly hemolyzed samples, contact is made with you and you are given the opportunity to take a new sample. Samples taken in Roche cell-free DNA and in Streck cf-DNA tubes are accepted.

Access to advice on referrals and interpretation of results can be found at info@lifegenomics.se and telephone +46-708583372. Any complaints or improvement proposals are communicated to us in the same manner and handled by us according to our procedures for deviations.

Personal data policy can be found at: <http://www.lifegenomics.se/om-oss/personuppgiftspolicy/>