

Produktdokument, kund

Dokumentnr: 0477-5

Sida: 1 (2)

Godkänd av: Eva Arkblad Giltig från: 2024-10-07

# Harmony NIPT sampling instruction english version

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

#### 1. LabPortalen Electronic referral

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

Log in to: https://login.labportalen.se/loggain.aspx?noLoginSimplified=true

Fill in patient information. Save. Send the electronic referral.

Let the patient sign the separate Patient Consent Form and place it along with the blood sample tubes in the sampling kit.

Reporting time is currently normally 4-9 working days.

### 2. Paper Referral

There is a possibility to use paper referrals (and upon request to receive response reports in paper via regular mail). If paper referrals are used, they should be folded together with the samples in the sampling kit.

# 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 LID and potential 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

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

#### 4. Pack the blood sample

Put the tubes back in the sampling kit as they come, together with the signed Patient Consent Form. Place the sampling kit in an envelope. **Note:** Several kits can be placed in the same envelope. Place the shipping note on the envelope. Seal tightly with staples or 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 <a href="mailto:info@lifegenomics.se">info@lifegenomics.se</a>

#### 6. Book transportation using DHL Express

Use DHL Express to send samples to Life Genomics. Samples should be sent with reference "Exempt human specimen" (not UN3373). Life Genomics can supply adhesive stickers with "Exempt human specimen". Ask DHL Express for envelopes. Use Life Genomics DHL Express account number for the charges: 957924787



Produktdokument, kund

Dokumentnr: 0477-5

Sida: 2 (2)

Godkänd av: Eva Arkblad Giltig från: 2024-10-07

# Harmony NIPT sampling instruction english version

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

**Note:** You must be available for DHL Express to pick up the package after the booking is made. You can also choose to turn the package in at any DHL Express Service Point.

## The following is provided by Life Genomics:

Sampling kit with 2 Roche cell-free DNA tubes (plastic). Patient information <u>Harmony Information to parents</u> and brochures. Login information to electronic system for referral and reporting.

Life Genomics is open weekdays 8.00 – 16.00, but often answer the phone outside these times.

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 <a href="mailto:info@lifegenomics.se">info@lifegenomics.se</a> and telephone +46 708 58 33 72. Any complaints or improvement proposals are communicated to us in the same manner and handled by us according to our procedures for deviations.

For important information regarding Harmony NIPT method's performance and limitations, see <u>Harmony Information to parents</u> which is provided upon request.

Personal data policy can be found at: <a href="https://www.lifegenomics.se/en/about-us/personal-data-policy/">https://www.lifegenomics.se/en/about-us/personal-data-policy/</a>