Module 4:
Sample Logistics

St George's University Hospitals NHS Foundation Trust

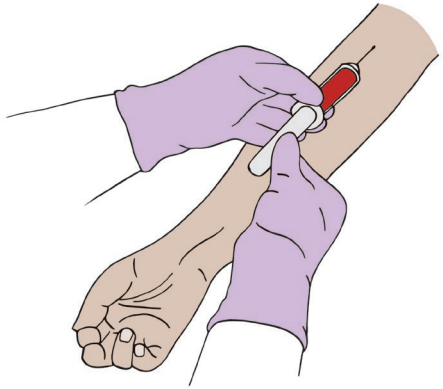
Module 4 will cover:

- Information provision for taking a blood sample
- Information on sample rejection
- Failed or delayed results
- MyNIPT® data exchange portal
- What happens in the laboratory

the SAFE test
St George's Antenatal Fetal Evaluation

Maternal blood sample

The SAFE test requires 10ml of maternal blood in either a Streck or EDTA tube:



- Streck cell-free DNA BCT CE tube:
  - Streck tubes have unique stabilisation properties and DNA remains stable at room temperature (6-37°c) for 14 days
- EDTA whole blood collection tubes:
  - DNA in the sample is stable for up to 8 hours at room temperature

Procedure for blood draw

- Ensure ‘Patient consent form’ is completed and signed by patient
- Check Streck tube is in date and undamaged prior to sampling
- Take sample using standard phlebotomy procedures
- If the tube fails to fill, discard and use another bottle
- Once the sample is taken, the sample should be inverted 10 times
- Safely discard used equipment appropriately
- Record patient information onto blood tube. This MUST include: Patient ID, date of birth, hospital number and date/time sample was taken
- Register sample on the MyNIPT® portal
- Store sample at room temperature – do not refrigerate or freeze

Sample rejection criteria

All samples that reach the laboratory have to meet strict criteria prior to being processed, otherwise they will be quarantined which causes a delay in a result.

- Samples ‘quarantined’:
  - Incomplete patient information

- Samples ‘rejected’:
  - Broken blood tubes
  - Incorrect tubes (not Streck or EDTA)
  - Compromised samples - including frozen or refrigerated sample
  - Clotted samples - from not inverting the tube
  - Old samples
  - Gestation age less than 10 weeks
  - Missing one or more of the 3 identifiers

Sample transportation

- Place blood tube into specimen mailing tube, then place into biohazard bag
- Place all samples and consent forms into the outer transport packaging provided, labelled with “SAFE test laboratory” and a UN3373 biological substance category B label
- All samples should be posted on the same day of sampling, to reduce delays in results
- Samples to be sent as per local agreements (post or through pathology)
- Order any collection components through the MyNIPT® portal system

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Why can samples get delayed?

- Each 10ml blood sample contains sufficient DNA for two laboratory analysis runs.

- If the first sample analysed fails to generate a result, a second analysis will be carried out by the laboratory. This will result in a delay of a minimum of 3 working days.

- The laboratory will inform the clinic if there is a delay in the sample via MyNIPT® portal.

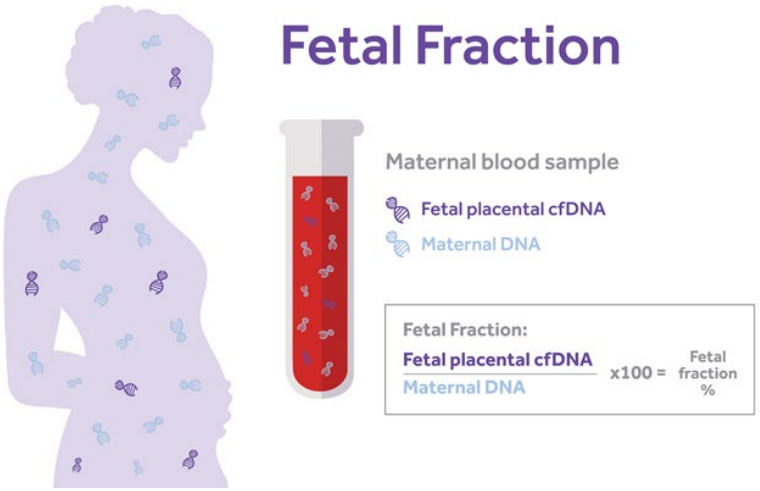
- If the sample fails following a second run, a re-draw could be potentially done. However, a diagnostic test may be discussed and recommended in view of the implications and time delay to another result for the patient.

Why can some samples fail?

- One reason for a failed sample is low levels of fetal fraction
- Very occasionally there could be a technical failure in the laboratory that would result in a sample fail
- The SAFE Laboratory recommend that women who have a failed NIPT test but have received a high chance combined or quadruple result should go straight for an invasive diagnostic test, as a failed result may indicate an affected pregnancy

Fetal Fraction

- Fetal fraction is the percentage of cfDNA in maternal blood that is of placental origin
- Fetal fraction is taken into account in the software and acts as an internal quality control before the result is given
- The SAFE test can generate an accurate result on samples with as little as 2% fetal fraction
- The SAFE test does not report the fetal fraction % on the screening test report



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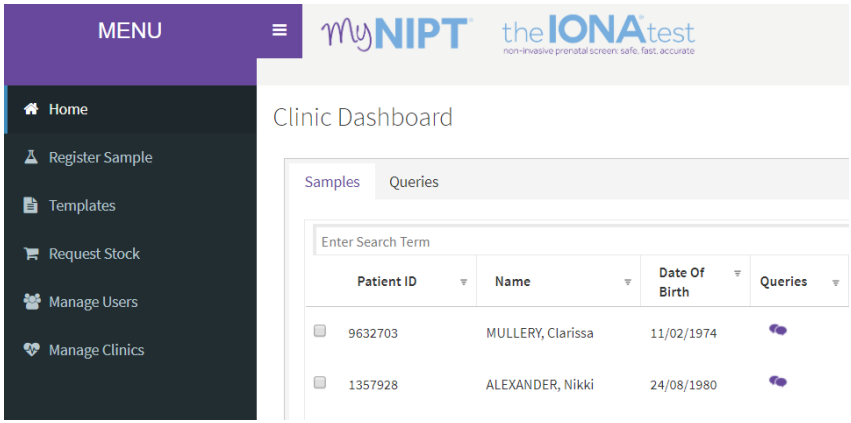
MyNIPT® portal

https://mynipt.com

Data exchange portal that enables the exchange of patient results easily and securely between the laboratory and clinician



- Register a sample
- Track the status of submitted samples and communicate with the laboratory
- High risk results are highlighted and alerts sent
- Order supplies via MyNIPT®
- Capability to monitor and track pregnancy outcomes