

# Module 4: Sample Logistics

Module 4 will cover:

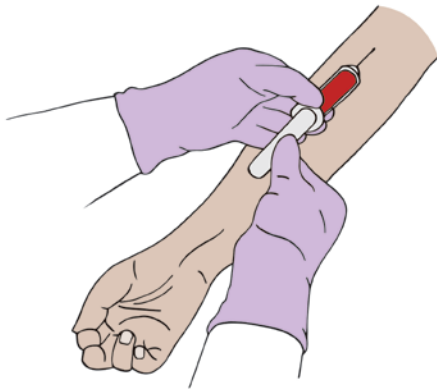
- Information provision for taking a blood sample
- Information on sample rejection
- Failed or delayed results
- MyNIPT<sup>®</sup> data exchange portal
- What happens in the laboratory

# 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 test request and 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



# 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<sup>®</sup> 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.



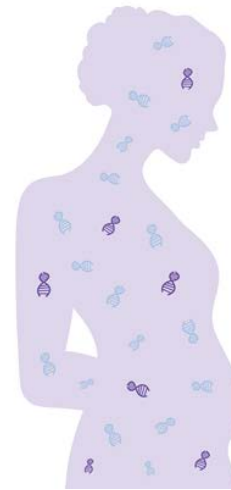
# Why can some samples fail?

- 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 high-risk women who have a failed test should go straight for an invasive diagnostic test such as amniocentesis or CVS as a failed result may indicate an affected pregnancy



# Fetal Fraction

- Fetal fraction is the percentage of cfDNA in maternal blood that is of fetal 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.



## Fetal Fraction



Maternal blood sample

 Fetal placental cfDNA

 Maternal DNA

Fetal Fraction:

$$\frac{\text{Fetal placental cfDNA}}{\text{Maternal DNA}} \times 100 = \text{Fetal fraction \%}$$



# 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



The screenshot shows the MyNIPT portal interface. On the left is a dark purple sidebar menu with the following items: Home, Register Sample, Templates, Request Stock, Manage Users, and Manage Clinics. The main content area is titled "Clinic Dashboard" and features a search bar labeled "Enter Search Term". Below the search bar is a table with the following data:

Patie... ID	Name	Date Of Birth	Process Status	Arriv... At Lab
20144589	BRANSON, Julia	19/08/1976	Analysing Sample	13/06/2016
1896640	GREY, Bethany	07/11/1978	Analysing Sample	09/06/2016