Trust Standard Operating Procedure

University Hospitals Plymouth NHS Trust

Cell free fetal DNA (cffDNA) testing for fetal Rhesus Status typing HD type

Issue Date	Review Date	Version
November 2020	October 2025	1

Purpose

The Purpose of this standard operating procedure

The purpose of this Standard Operating Procedure is to provide all clinical staff working within Maternity Services clear guidance of the cffDNA service.

Who should read this document?

All midwives

All maternity staff working in maternity services

Key Messages

To maintain safe and effective care to all women

Accountabilities	
Owner	Liza Rose
Review	Maternity Assurance Group, Women's and Children's Services
Ratification	Clinical Governance Lead – Alex Taylor
Dissemination (Raising Awareness)	All staff working within the Obstetric Service line All theatre staff covering Maternity Theatres
Compliance	Maternity Assurance Group

Links to other policies and procedures

Administration of Anti-D Immunoglobulin

Version History

1	October 2020	Documented created and approved

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Standard Operating Procedure (SOP)

1 Introduction

This standard operating procedure details the appropriate care pathway for Rhesus negative women who require cffDNA testing.

2 Definitions

cffDNA - Cell Free Fetal DNA Test

RAADP - Routine antenatal Anti-D prophylaxis

NHSBT - National Health Services Blood Transport

3 Regulatory Background

NICE recommend high-throughput non-invasive prenatal testing (NIPT) for prevention of fetal Rhesus Haemolytic Disease (RHD) as a cost-effective option to guide antenatal prophylaxis with anti-D immunoglobulin (anti-D Ig).

https://www.nice.org.uk/guidance/dg25

4 Key Duties

- At the time of booking the community midwife will counsel women who have Rh D Negative blood group and will offer the cffDNA test at the time of the first trimester screening/dating scan.
- The NHSBT patient information leaflet "**Rh D negative mother's blood test to check her unborn baby's blood group"** is included in all booking packs.
- The Screening midwives will identify all women who are Rh D negative and highlight on first trimester lists.
- Midwife sonographers will ask Rh D negative women at time of scan (when blood group available) if they wish to have cffDNA test.
- Counselling and consent of pregnant women will be completed by a midwife.
- Phlebotomy will be undertaken by midwives or maternity care assistants (MCA) within Women Day Services (WDS).
- The antenatal clinic (ANC) midwife will enter all Rh D negative women details and results onto data base (stored on G drive).

- WDS will check all deliveries on a weekly basis to confirm babies' blood group as failsafe in the system. Any incidents will be reported to screening midwife and entered on DATIX.

5 Identification and Consent

- The routine antenatal screening bloods, which include blood group, must be taken at the time of the community midwives booking visit. The antenatal screening midwives will review all bloods prior to the dating/first trimester scan.
- All women identified as having Rh D negative blood status will be highlighted on the scan lists.
- At time of the dating scan appointment the midwife sonographers explain all available antenatal screening blood results to the woman and file the blood results in the notes.
- Rh D negative women are then offered the choice of having the cffDNA blood test.
- The test is optional.
- Women can consent to having the test and then request to have prophylactic Anti D (irrespective of whether the baby is predicted to have a Rh D negative blood group). Consent is confirmed by the signature of a midwife on the management sticker on page 13 of the notes.
- When the patient agrees to the test the ANC midwife will be notified of the patient decision and the blood samples will be taken by a MCA or midwife.
- Women who decline the cffDNA blood test and decide at a later gestation to have the test can be referred back to Day assessment ward (DAW) by their community midwife anytime **up to 28+0 weeks.**

Please note: The cffDNA test is not available after 28+0 weeks.

<u>Documentation</u>

- A photocopy of the cffDNA blood request form will be filed in the patient's notes and the sample is sent to blood bank.
- A sticker identifying that the patient has had cffDNA testing will be placed on the front of the notes.
- A management sticker will be placed on the management plan on page 13.
- The management sticker will be completed by the community midwife at the 16 week appointment.
- The woman will receive a letter with the cffDNA results.

It is the community midwives' responsibility at the 16 week appointment to check the results have been sent and are complete. When the midwife has confirmed results are available they must complete the cffDNA test results sticker on the management plan in the maternity notes (page 13).

6 Sampling procedure

Sample requirements for cffDNA

- 6ml maternal blood collected in EDTA tube from Rh D negative pregnant women who have not made anti-D antibodies (EDTA pink blood bottles>4mls are available on WDS specially for cffDNA). If not available, 2 full standard EDTA tubes are required.
- Estimated delivery date (**from dating scan)** must be written on the request form.
- Gestation must be at least **11+2 weeks** at time of venepuncture or the sample will be rejected.
- The sample tubes must not be opened following blood collection.
- The sample must not be used for any testing prior to being received at the Bristol laboratory.
- The sample tube should be stored at room temperature.
- The sample tube must be labelled, dated and signed by the person taking sample.
- Labels pre-printed prior to phlebotomy e.g. addressograph labels are not acceptable on samples. The laboratory however, will accept addressograph labels on request forms providing they do not obscure other vital details.
- Samples must have handwritten labels. Repetition of above
- Hand written alterations on the either the sample or request form may make the sample invalid. Any minor alterations must be initialled by the person taking the sample to be acceptable for testing.
- A photocopy of the request form must go in patient's notes.
- Ensure that the cffDNA stickers are placed on the front of notes and page 13 of management plan in handheld maternity notes.

7 Follow up and documentation of results

- Results will be available after 14 days.
- cffDNA results are sent to blood bank by Bristol laboratory. A paper copy of the cffDNA test results will be delivered to ANC by blood bank.
- WDS to ensure that a copy of the results is sent out via daily communication, to the community teams.

Please note: Results will be made available on iSOFT.

Results and Management

There are three possible results and management should be as follows:

Women with:

Inconclusive results will be managed as if the fetus is Rh positive and the mother will be offered routine prophylactic Anti-D at 28 weeks and after any sensitising event. The test **will not** be repeated.

Positive results will be managed as if the fetus has Rh positive status and patient will be offered routine prophylactic Anti-D at 28 weeks and after a sensitising event.

Negative results where the status of the fetus is Rh negative **should not** be offered Anti-D but the patient can still request to receive anti-D if she desires. Please ensure the request is clearly documented in the handheld notes in the management plan and on the cffDNA data base.

Results not available at time of first trimester scan

- The screening team follow up all women who have blood taken at the time of scan or taken in the community immediately before the scan and are not available.
- They will inform ANC of those women who are Rh D negative.
- The ANC midwife will contact the patient to offer the cffDNA blood test and arrange an appointment if accepted.
- The community midwife must not take the bloods themselves. An appointment must be made for the patient to attend WDS.

Communication of results to Patient and Health Professionals:

A copy of the results and a letter explaining the cffDNA results and subsequent management during pregnancy will be sent to the woman, GP and filed in the main hospital notes. The copy of the letter will be sent via community messages to the community midwife.

Routine bloods at 28 weeks

All women **must** have the routine 28 weeks blood taken, including Blood Group and FBC, and results followed up as normal.

cffDNA Database

All Rh D Negative patient details, information re: acceptance of, or declined testing and the cffDNA results will be recorded on the Rh D Negative /cffDNA test database stored on the Fetal Medicine drive.

8 Management at Delivery

For failsafe purposes, cord bloods are to be performed at delivery on **all** Rh D negative women **regardless of cffDNA results**.

The WDS midwife will enter all cord blood results to the database.

9 Audit

The WDS database will be used for the purpose of a failsafe and for ongoing audit of patient predictive accuracy rates and update of cffDNA. The audit will be presented at MAG annually.

10 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Maternity Governance team and ratified by the Maternity Assurance Group.

Non-significant amendments to this document may be made, under delegated authority from the Director of Midwifery, by the nominated author. These must be ratified by the Director and should be reported, retrospectively, to the group.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

11 Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

12 Reference Material

https://www.nice.org.uk/guidance/dg25