Fetal RHD Screen (cffDNA)

Test Request Form

BLOOD GROUP GENETICS LABORATORY

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For RhD-negative pregnant women with NO alloanti-D.

Please supply ≥8ml EDTA-coagulated whole blood. Store and Transport at room temperature.

Please ensure there are at least three (3) points of matching identification on this form and sample tube(s). Samples must be either hand-written at time of phlebotomy, or labelled using demand-printed labels.

PATIENT'S DETAILS	ATIENT'S DETAILS (shaded areas are not essential. Demand-printed label will suffice if it contains other required information)		
Surname		EDD, Gestation of Current Pregnancy	
First Name		Details of Previous Pregnancies	
(Maiden Name)		Known Blood Groups	
Gender		Known Antibodies	
DoB		Hospital	
MRN		Consultant	
Ethnic Origin		Sample Type, Date & Time	
Address		Referring Laboratory Sample Number	
Clinical Details and Other Useful Information (e.g. transfusion, transplantation, medication, diagnosis).			
Requester's Details			
Print Name	Signature	Position	Date
For IBTS Use Only			
Sample Labelled		Date & Time Received by IBTS	IBTS Laboratory Number
Comments			•

Hospitals wishing to refer for the first time must contact the Blood Group Genetics Laboratory before sending the sample to discuss the appropriateness of the proposed investigation.

Sample Requirements

- Maternal peripheral blood (≥8ml) collected in an EDTA tube from RhD-negative pregnant women, at Booking.
- 2. These women MUST NOT have made alloanti-D.
- 3. The pregnancy should be at ≥11 week's gestation.
- 4. The sample tube **MUST NOT** be opened following phlebotomy.
- 5. The sample **MUST NOT** be used for any other testing.
- 6. The sample tube **MUST** only be stored at room temperature.
- 7. The sample tube **MUST** be labelled with the following information:
 - a. Three unique sample identifiers including: Full name (first name and surname), date of birth, and hospital number (these MUST be identical to the Test Request Form).
 - b. Expected date of delivery and gestation (indicate if scan-confirmed or estimated by LMP).
 - c. Samples MUST be labelled, dated and signed by the person taking them.
- 8. Addressograph labels are **NOT** acceptable on sample.
- 9. Samples MUST either have handwritten labels, or demand-printed labels produced at the time of phlebotomy.
- 10. Hand written alterations on either the sample or Test Request Form may make the sample invalid for testing.
- Any minor alterations must be initialled by the person taking the sample to be acceptable for testing.

Transport Requirements

- Samples MUST arrive at the IBTS to allow processing within 5 calendar days of phlebotomy.
- 2. Samples MUST be stored and transported at room temperature.
- 3. Samples MUST be transported in an appropriate IATA-compliant container and labelled with an IBTS address label.

Test Guide

The Fetal *RHD* Screen is designed to determine the *RHD* type of cell-free DNA in maternal peripheral plasma. It is to be used as a guide for administration of prophylactic anti-D (for all *Potential Sensitising Events*, and second trimester *Routine Antenatal Anti-D Prophylaxis* (RAADP)).

The assay used by the IBTS targets *RHD* exons 7 and 10, and is designed and optimised as a screen to identify the presence of *RHD* sequences in cfDNA extracted from maternal plasma. Assay sensitivity (and therefore reduced false negative) is prioritised. False positive fetal *RHD* predictions may occur and are likely to be due to silenced *RHD* or *RHD-RHCE* hybrid genes (e.g. $RHD\Psi$ in Africans), or rarely due to vanishing twins.

Similarly silenced *RHD* or *RHD-RHCE* hybrid genes present in cfDNA of maternal origin, will mask any fetal cfDNA present; determination of fetal *RHD* type in these cases will not be possible.

The test is accurate from 11 weeks gestation on. Results will be reported as follows:

- If RHD-positive, a report will be issued stating 'RHD-positive Fetus' (irrespective of gestation)
- If RHD-negative AND ≥11/40 weeks, a report will be issued stating 'RHD-negative Fetus'
- If RHD-negative AND <11/40 weeks, a report will be issued stating 'Inconclusive Result' and requesting a repeat sample taken at ≥11/40

Please refer to User Guide for additional information.

The following can be found at www.giveblood.ie/Clinical-Services/Blood-Group-Genetics;

- Red Cell Genotyping Test Request Form (BT-0637 RED)
- Fetal RHD Screen Test Request Form (BT-0638 YELLOW)
- IBTS Address Label Template
- User Guide (IBTS/BGG/UG/0001)
- Other useful information