An investigation template for discrepant cell-free fetal DNA (cffDNA) results

The following template has been developed to assist hospital laboratories in investigation where cord D-types are discrepant with D-type predicted by cffDNA screening. Laboratories may wish to amend as appropriate for their own use.

Please report all suspected cffDNA discrepant results to the reference laboratory who provided the result and to SHOT as an anti-D Ig error. Further guidance can be found at https://www.shotuk.org/reporting/

Discrepant cell-free fetal DNA (cffDNA) result investigation template for hospital transfusion laboratories

The relevant section of this form should be completed by transfusion laboratory management staff in a timely manner for all cases where there is a discrepancy noted in the fetal D-type predicted by cffDNA screening and the D-type at cord testing. An incident should be raised as per local practices in Quality Management Systems and the relevant teams (maternity risk & governance team and midwives) informed so that appropriate actions can be taken.

Mother unique identifier (Hospital/NHS number):

Mother name: **Mother DOB:**

cffDNA result: **cffDNA sample number and date:**

Baby unique identifier: **Cord D-type:**

Cord sample number where available and date:

The completed document to be saved in mother's record on LIMS/patient's notes.

Apparent false negative cffDNA result

Investigation	Outcome
Consideration of wrong blood in tube (WBIT) (cord sample): • Is the ABO group feasible? • Were any other cord samples taken at or around the same time? • FBC parameters of CORD sample match maternal sample? If no, consider WBIT of cffDNA sample Discussed with midwife if appropriate (state name):	
Testing errors: • Cord/baby identification details match on sample and LIMS? • Laboratory barcode matched on sample and LIMS? • Analyser results confirmed correct for cord sample? • Cord D-type confirmed with alternative method (e.g., tube group)?	
Gestation date of mother at time of sample for cffDNA screening (weeks). Note: <11+3 weeks may not have sufficient fetal DNA for screening and hence results may not be reliable	
Evidence of HDFN	
Baby DAT	

Maternal alloantibodies	
Anti-D Ig administered post-delivery (date/time/dose)	
Local incident reference number	
Date reported to reference laboratory	
Date mother and cord samples sent to reference laboratory	
SHOT reference number	
Outcome of reference laboratory review	
Outcome of investigation	
Name, signature and date (Transfusion management)	

Apparent false positive result

Investigation	**Outcome**
Consideration of wrong blood in tube (cord sample): • Is the ABO group feasible? • Were any other cord samples taken at or around the same time? • FBC parameters of CORD sample match maternal sample? If yes, consider WBIT of cord sample Discussed with midwife if appropriate (state name):	
Testing errors: • Cord/baby identification details match on sample and LIMS? • Laboratory barcode matched on sample and LIMS? • Analyser results confirmed correct for cord sample? • Cord D-type confirmed with alternative method (tube group)?	
Cord Rh/K phenotype result Weak/partial D testing result	
Anti-D Ig issued post-delivery if indicated (time/date/dose)	
Local incident reference number	
Date reported to reference laboratory	
SHOT reference number	
Outcome of investigation	
Name, signature and date (Transfusion Management)	

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