# Appendix 1: An Audit Tool to Assess Compliance with the BCSH Guidelines for Blood Grouping and Red Cell Antibody Testing In Pregnancy

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| **Section** | **Criteria** | **Compliance Y N N/A** | **Action Required** | **To be completed by:** |
| **Section 1** | **Consent, Samples And Request Forms** |  |  |  |
|  | Samples for antenatal screening are identified to the same standard BCSH guideline for pre- transfusion compatibility procedures in blood transfusion laboratories. |  |  |  |
|  | Samples are dated, labelled and signed by the person taking them, in the presence of the woman who should be positively identified. Sample Labels pre-printed away from the phlebotomy procedure are not be used. |  |  |  |
|  | Details (including date and dose) of any previous administrations of anti-D Ig given in the current pregnancy are recorded on the laboratory request form |  |  |  |
|  | The woman’s clinical history particularly of HDFN and previous transfusions is recorded on the laboratory request form |  |  |  |
| **Section 2** | **Laboratory Tests** |  |  |  |
|  | All laboratory testing procedures are validated in  compliance with published guidelines |  |  |  |

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| **Section** | **Criteria** | **Compliance Y N N/A** | **Action Required** | **To be completed by:** |
|  | ABO and D grouping is performed in accordance  with the guidelines for compatibility procedures in blood transfusion laboratories. |  |  |  |
|  | If clear-cut positive results are not obtained in D typing, women are classified as D negative until the D status is confirmed. |  |  |  |
|  | All pregnant women found to be D negative are given written information about their D negative status and the importance of anti-D Ig prophylaxis.  The D status is clearly recorded in the notes. |  |  |  |
|  | The screening cells and methods used for red cell antibody screening comply with the guidelines for compatibility procedures in blood transfusion  laboratories; BCSH 2012-b. |  |  |  |
|  | Once red cells antibodies are identified in pregnancy, the identification process is repeated with each additional sample to exclude any  additional clinically significant maternal antibodies. |  |  |  |
|  | The concentration of each antibody capable of causing HDFN is assessed independently. For specificities where there is a national standard preparation, quantification is undertaken. Other  antibody specificities are measured using titration. |  |  |  |
|  | Where possible each sample for titration is tested in parallel with the previous sample and the results compared to identify significant changes in  antibody concentration. |  |  |  |

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| **Section** | **Criteria** | **Compliance Y N N/A** | **Action Required** | **To be completed by:** |
|  | Pregnant women with anti-D, -c –E and –K antibodies are offered non-invasive fetal blood grouping using cell-free fetal DNA (cffDNA) from maternal plasma.  This is performed at a gestation recommended by the reference laboratory used.  cffDNA tests are requested by obstetricians or fetal medicine specialists who can explain the implications of the test findings in the context of the full history and investigation findings. |  |  |  |
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| **Section 3** | **Antenatal Testing Protocols** |  |  |  |
|  | All pregnant women who are D negative are considered for prophylactic anti-D Ig for potentially sensitising events as defined in guidelines for the  use of anti-D Ig for the prevention of HDFN. |  |  |  |
|  | All pregnant women are ABO and D typed and screened for the presence of red cell antibodies both early in pregnancy and at 28 weeks gestation,  before the administration of RAADP. |  |  |  |
|  | In women with no red cell antibodies present at 28 weeks gestation, no further routine antenatal blood  grouping or antibody screening is undertaken. |  |  |  |
| **Section 4** | **Red Cell Antibodies Detected In Pregnancy.** |  |  |  |

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| **Section** | **Criteria** | **Compliance Y N N/A** | **Action Required** | **To be completed by:** |
|  | All women who have previously had a baby affected by HDFN are referred before 20 weeks gestation to a fetal medicine specialist for advice and for assessment of fetal haemolysis,  irrespective of antibody concentration or specificity. |  |  |  |
|  | The laboratory keeps clear records of anti-D Ig  administration. |  |  |  |
|  | All anti-D detected in pregnancy should be quantified by CFA, or tested by a method that has been extensively validated against quantification, and there is a clear procedure to distinguish between immune and passive anti-D Ig, including review of clinical history and previous laboratory  results. |  |  |  |
|  | When there is doubt as to the passive or immune nature of anti-D, concentration is monitored and prophylactic anti-D Ig offered, where indicated, until  the nature of anti-D is established. |  |  |  |
|  | A reference centre confirms antibody specificity in  women with apparent anti-C+D. |  |  |  |
|  | Cases of anti-D and anti-c are referred to a fetal medicine specialist if the antibody concentration reaches the critical level and/or the level is rising significantly. The antibody concentration is assessed serologically at 4 weekly intervals to 28 weeks gestation and at fortnightly intervals thereafter until delivery, unless advised otherwise  by clinicians undertaking serial MCA Doppler. |  |  |  |

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| **Section** | **Criteria** | **Compliance Y N N/A** | **Action Required** | **To be completed by:** |
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|  | Cases of anti-K or other Kell system antibody [unless the father is confirmed to be antigen negative] are referred to a fetal medicine specialist when the antibody is first identified. The antibody strength is assessed serologically at monthly intervals to 28 weeks gestation and at fortnightly intervals thereafter until delivery, unless advised otherwise by clinicians undertaking serial MCA  Doppler. All cases |  |  |  |
|  | Clinically significant antibodies, other than anti-D, - c or -K, are excluded or, if present, assessed by titration, at the booking appointment and at 28 weeks gestation. Where the titre is>32 and/or there is a past history of HDFN, referral to a specialist in  fetal medicine is made for further assessment. |  |  |  |
| **Section 5** | **Reports Of Laboratory Investigations** |  |  |  |
|  | Reports inform the clinician[s] of the significance of the antibodies, with respect to the development of HDFN and transfusion problems. |  |  |  |
| **Section 6** | **Action At Time Of Birth** |  |  |  |
|  | All babies born to women who have clinically significant antibodies are closely observed for evidence of HDFN. A DAT is performed, and haemoglobin and bilirubin concentrations are  measured. |  |  |  |

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| **Section** | **Criteria** | **Compliance Y N N/A** | **Action Required** | **To be completed by:** |
|  | A DAT is not routinely performed on cord samples  of D positive babies born to D negative women leading to unnecessary additional investigations. |  |  |  |
|  | D negative women with no immune anti-D have an initial FMH test at delivery and follow up testing if required, in accordance with BCSH guidelines for  estimation of FMH. |  |  |  |
| **Section 7** | **Audit** |  |  |  |
|  | Audits of compliance with the clinical and laboratory aspects of these guidelines are undertaken on a continuing basis and all variations or concerns addressed in a timely manner. |  |  |  |

See text of guidelines for references and the grades of evidence.