NHS
Blood and Transplant

Reagents

Meeting your serology needs

REAGENTS

NHS Blood and Transplant Reagents – meeting your serology needs

NHSBT Reagents meets your serology needs by manufacturing a portfolio of transfusion related diagnostic reagents, supporting our NHS customers as well as NHSBT Red Cell Immunohaematology and donor testing services. These are available to our customers from our specialised manufacturing site at Speke, Liverpool and a specialist facility in Filton, Bristol.

The advantages of working with NHSBT Reagents:

- Processes are developed and managed by highly experienced Red Cell Immunohaematology Biomedical Scientists and Reagents manufacturers.
- We evaluate our reagents using standard blood transfusion equipment including those supplied by the leading equipment manufacturers.
- We offer a wide range of products which are available in different diluents and barcoded for the use on commercial analysers.
- We ensure that our batches are consistent and comply with or exceed guidelines.
- We offer customer service and technical support to you and your staff.
- We offer bespoke evaluation services to support commercial partners.

Helping your team to achieve your high standards

Internal Proficiency Exercise (IPEx):

- We know that your team also seeks to be the best that they can be- NHSBT Reagents can help you achieve this by offering you an internal proficiency exercise (IPEx).
- IPEx is the ideal tool to use for competency assessments and is designed to provide an enhanced learning experience. Each exercise is accompanied by CPD question sets with references to the relevant guidelines and scientific papers. The product is available six times a year and typically consists of three plasma and three red cell samples. Results and answers are sent to a designated email address and can be used to guide and coach staff through the exercise.

Customer focused activities

Capacity and developments

- We use lean methodology to enable us to be even more responsive to customer requests. NHSBT Reagents has validated contingency arrangements to further ensure guaranteed continuity of supply to our customers.

Customer service

- Our customer focussed Reagents team will work with you to ensure we can provide services and products tailored to your needs. We welcome your comments and feedback and use these inputs to improve our products and services accordingly.
- We welcome discussions regarding manufacture of current hospital laboratory in-house reagents to allow conformance with the IVD regulation (EU)2017/746.

Ordering reagents

- You can find the full range of our products on our website.

Quality and compliance

ISO13485 certification

- We have ISO13485 certification, accrediting our quality system for the manufacture of reagents for transfusion testing. A copy of the certificate can be found on our website.

CE marked reagents

- All our reagents are CE marked and comply with the standards laid down in the Guidelines for the Blood Transfusion Services in the U.K. (current edition). They are prepared to the best standards of practice in accordance with the EU IVDD directive.

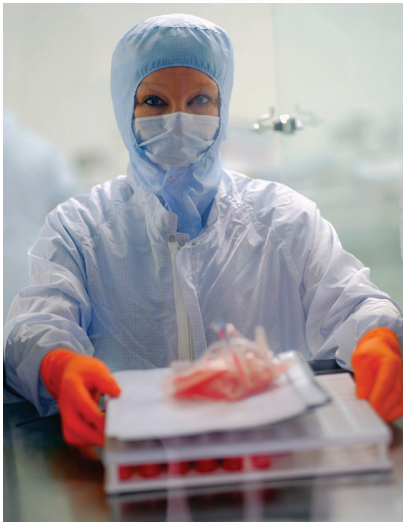
Certificates of conformance

- We supply you with a certificate of conformance for each batch of our CE marked products. You can find these on our website in the 'Certificates of conformance' section.

Manufacturing process

NHSBT ensures that all of our products are manufactured following GMP, ISO13485 and IVDD requirements.

- The components used in manufacture are all tested before use.
- In-process checks during the production cycle ensure consistency of the final product.
- The product processing and decant areas are environmentally monitored to ensure the aseptic techniques are not compromised.
- Line clearance techniques are employed to prevent cross contamination of products.



Selection of material

- Only donations from blood donors that have been fully tested to Red Book standards are used for reagent manufacture.
- Donations are selected which match our standard national specifications. These comply with or exceed Red Book and European Common Technical Specifications.

Pre-release

- All products are placed in quarantine until pre-release testing has been performed.
- Serological testing of the bottled product includes repeat phenotyping and testing with weak antibodies.
- Bottles are also checked for the accuracy of filling and labelling.

Post-release

- Further checks are made on or just after the expiry to assure products remain fit-for-use.
- Any complaints are fully investigated and recorded.
- Defective bottles are replaced and a system is in place for product recall.

Products

Cells for antibody screening & identification

2 cell screen

Meets the current UK & European guideline requirements; OR_1R_1 & OR_2R_2

Cells homozygous for major antigens, Rh, Fy, Jk, MNS.

3 cell screen

As for the 2 cell screen but includes Cw & Kpa antigens and an additional Orr cell.

rr screening cells

These are produced especially for use when testing antenatal patients post anti-D Immunoglobulin injections. These D negative cells express all the other major antigens with homozygous expression in order to exclude the presence of other significant antibodies. There is an additional subset of an Or'r and Or''r also available to investigate the presence of anti-C and anti-E respectively.

Antibody identification panels

Two different 10 cell panels, both exceeding the requirements of the British Society for Haematology and Guidelines for the Blood Transfusion Services in the UK, available as both enzyme treated and non-enzyme treated consistently providing users with the ability to resolve mixtures of antibodies. The ID panel profiles are available on our website under the heading Product Profiles.

These cells are provided in the following formats:

2 cell screen	3% in Alsevers (PR101) 0.8% in CellStab (PR102) 0.8% in CellMedia (PR103)
3 cell screen	3% in Alsevers (PR121) 0.8% in CellStab (PR122) 0.8% in CellMedia (PR123)
rr screening cells	0.8% in CellStab (PR106) 0.8% in CellMedia (PR108)
r'r, r''r subset	0.8% in CellStab (PR107) 0.8% in CellMedia (PR109)
ID Panel 1	3% in Alsevers (PR144) 3% in Alsevers (PR154) enzyme treated 0.8% in CellStab (PR143) 0.8% in CellMedia (PR163) 0.8% in CellStab (PR153) enzyme treated 0.8% in CellMedia (PR173) enzyme treated 1.5% in LISP (PR146)

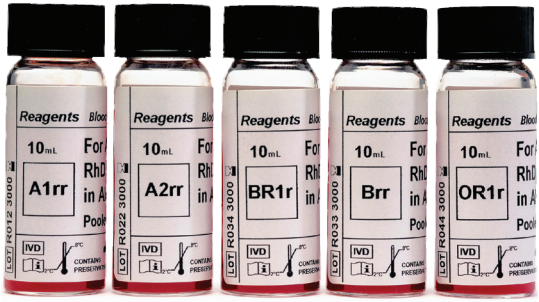
And to customers who order ID Panel 1 an additional Panel:

ID Panel 2	3% in Alsevers (PR141) 0.8% in CellStab (PR142) 0.8% in CellStab (PR152) enzyme treated

ABO & Rh control/reverse grouping cells

Cells provided ready to use for reverse grouping and for use as controls

3% in Alsevers	A_1rr (PR012), A_2rr (PR022), Brr (PR033), BR_1r (PR034), OR_1r (PR044)
0.8% in CellStab	A_1rr (PR014) Brr (PR035), OR_1r (PR045)
0.8% in CellMedia	A_1rr (PR015) Brr (PR036), OR_1r (PR046)



Products manufactured in CellStab and CellMedia are barcode labelled to be fully identifiable by the appropriate manufacturers automated technology and are validated for use on these systems.

Products for further investigations

Papain

Red blood cells can be treated with papain and then used to test serum/plasma to enable identification of alloantibodies. This material is provided frozen in 5mL volumes and has been standardised using the Azo-albumin technique. It is confirmed as fit for use using weak anti-Rh sera by standard serological techniques.

ZZAP

This product is intended to be used in the resolution of complex serological investigations involving IgG autoantibodies. ZZAP is a mixture of cysteine-activated proteolytic papain and dithiothreitol (DTT). It is used to enhance the dissociation of red cell-bound IgG by causing IgG molecules to lose their integrity so that the treated red cells can be used for absorptions. It is supplied frozen as a kit containing 0.2M DTT and 1% papain.

Dithiothreitol:

0.2M DTT	For the removal of Kell system antigens from the surface of human red cells
0.01M DTT	For the differentiation of IgM and IgG antibodies.

Fluorescently labelled antibodies for FMH investigations.

FITC conjugated BRAD 3 (anti-RhD), FITC Conjugated AEVZ 5.3 (isotype matched negative control) and PE conjugated BIRMA 17C (for gating of neutrophil contamination) used for determination and control of tests for Feto-Maternal Haemorrhage.

Products for Laboratory QC and QA

Weak antibody controls

We provide a series of weak human antibodies, anti-Fy^a, anti-c, anti-K, standardised against NHSBT screening cells to give a titre of approximately 4; the traditional weak anti-D (≤0.1 IU/mL) plus AB serum for use as a negative control.

- Weak antibody controls – anti -Fy^a (PN044); anti-c (PN042); anti-K (PN043)
- Weak anti-D control (≤0.1 IU/mL PN046)
- AB serum (PN061)

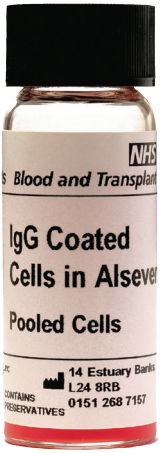
IgG coated, antiglobulin test control cells (PR092)

These are available for laboratories using tube IAT.

Whole blood controls (PR051)

These are intended for use in QC of automated systems. 2 samples of 33% cells in human plasma are provided; group A and group B, RhD positive and negative.

- One sample contains weak anti-D and the other sample contains weak anti-K.



For general information and the full product range visit our website or contact our Reagents Customer Services Team:

- Phone **0151 268 7157**
- E-mail: **reagents@nhsbt.nhs.uk**
- Website: **www.blood.co.uk/reagents**

For more information

Additional copies of this leaflet and any other further information can be obtained from the NHSBT Customer Services team or visit the Reagents area of the Website. The address is: **www.blood.co.uk/reagents**

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