

NHSBT Reagents

Meeting your serology needs

A microscopic view of numerous red blood cells, appearing as reddish-orange biconcave discs, floating against a darker red background. A blue wavy line separates the white header area from this image.

Vision: maximise the efficacy of blood transfusion through the provision of innovative, high quality, commercially aligned reagents

Caring Expert Quality

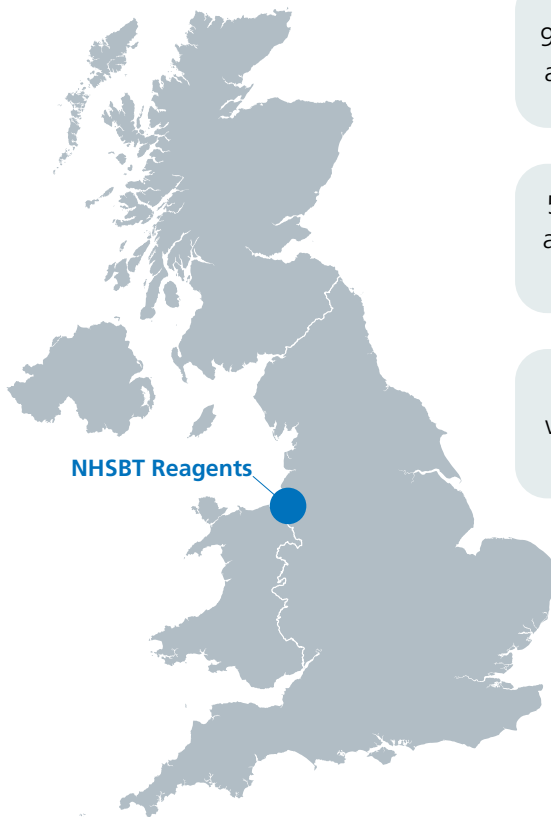
Who we are and what we do

NHS Blood and Transplant (NHSBT) is a Special Health Authority dedicated to saving and improving lives.

NHS Blood and Transplant (NHSBT) provides a blood and transplantation service to the NHS, looking after blood donation services in England and transplant services across the UK.

NHSBT Reagents is a specialist department within NHSBT that designs, manufactures and distributes in vitro diagnostic medical devices for transfusion and transplantation investigations, including blood grouping control reagents.

The products manufactured by the NHSBT Reagents department are sold to the NHS, private hospitals, pathology networks and commercial companies.



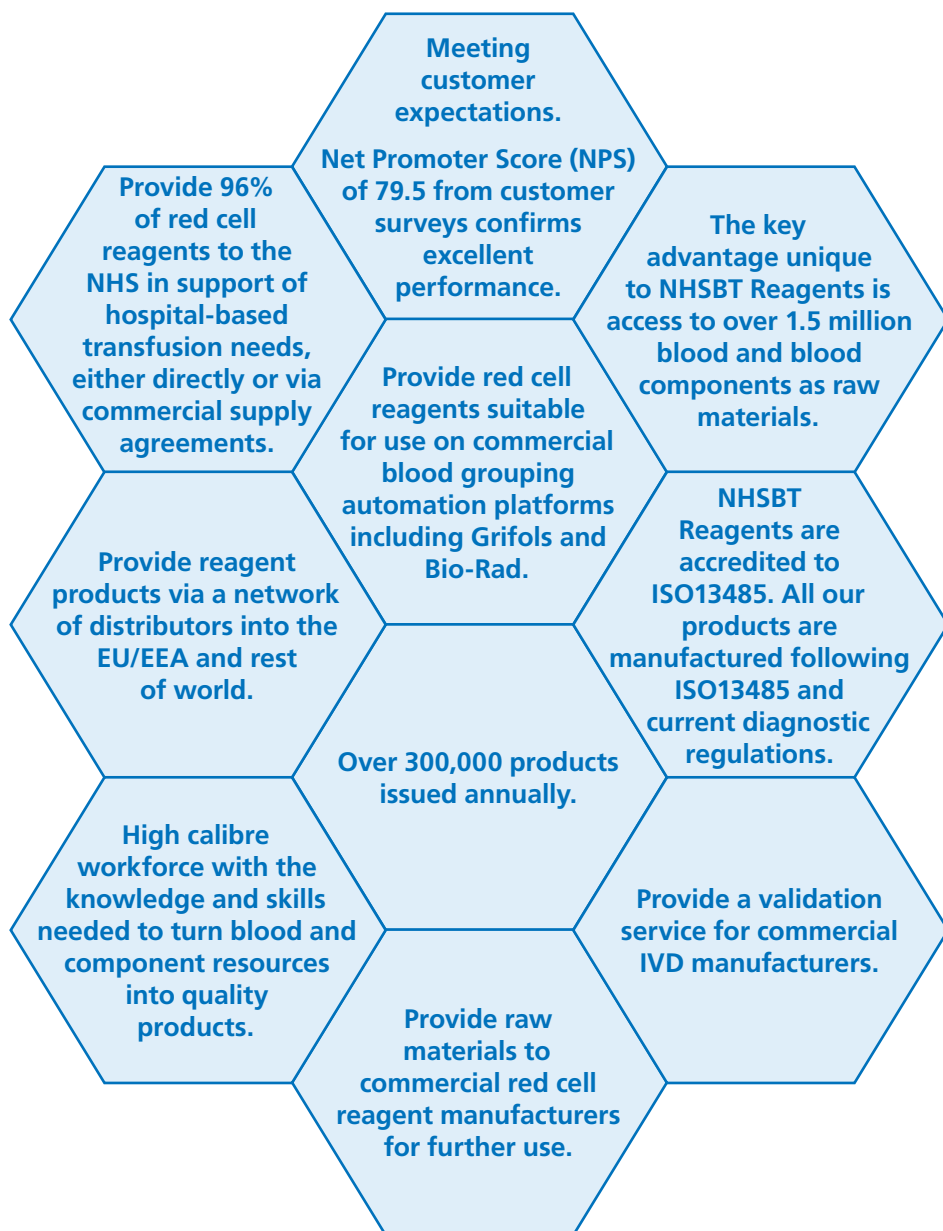
93.5% of NHSBT Reagents' products are sold to, and used within, the UK

5.5% of NHSBT Reagents' products are sold through distributors outside of the UK

1% of NHSBT Reagents' business is with commercial IVD manufacturers within the UK and Europe

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What we deliver



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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 products 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 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.



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Consistent and accurate manufacturing process

NHSBT Reagents ensure that all our products are manufactured following ISO13485 and current diagnostic regulation 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 Guidelines for the Blood Transfusion Services in the UK (Red Book standards) are used for reagent manufacture.
- Donations are selected which match our standard national specifications. These comply with or exceed Red Book guidelines.

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, expiry to assure products remain fit-for-use.
- Any complaints are investigated and recorded.
- Defective bottles are replaced, and a system is in place for product recall.

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Product range

Red cell reagents

All cells are manufactured on a 4-weekly cycle and meet the required regulatory requirements for the territory they are supplied to. Products manufactured in CellStab and CellMedia are barcode-labelled to be fully identifiable by the appropriate manufacturer's automated technology and are validated for use on these systems.

ABO and Rh control/reverse grouping cells

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

Description	Product Code
3% in alsevers	A ₁ rr (PR012), A ₂ rr (PR022), Brr (PR033), BR ₁ r (PR034) and OR ₁ r (PR044)
0.8% in CellStab	A ₁ rr (PR014), Brr (PR035) and OR ₁ r (PR045)
0.8% in CellMedia	A ₁ rr (PR015), Brr (PR036) and OR ₁ r (PR046)

Cells for antibody screening & identification

2-cell screen

Meets the current UK & European guideline requirements; OR₁R₁ & OR₂R₂ Cells homozygous for major antigens, Rh, Fy, Jk, MNS.

Description	Product Code
2-cell screen 3% in Alsevers	PR101
2-cell screen 0.8% in CellStab	PR102
2-cell screen 0.8% in CellMedia	PR103

3-cell screen

As for the 2-cell screen but includes C^w & Kp^a antigens, although these are not guideline requirements, and an additional Orr cell.

Description	Product Code
3-cell screen 3% in Alsevers	PR121
3-cell screen 0.8% in CellStab	PR122
3-cell screen 0.8% in CellMedia	PR123

rr screening cells

These are produced especially for use when testing antenatal patients post anti-D Ig injections. These D negative cells contain 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.

Description	Product Code
rr screening cells 0.8% in CellStab	PR106
rr screening cells 0.8% in CellMedia	PR108
r'r,r''r subset cells 0.8% in CellStab	PR107
r'r,r''r subset cells 0.8% in CellMedia	PR109

Antibody identification panels

Two different 10 cell panels, both meeting the requirements of the Guidelines for the Blood Transfusion Services in the UK, available as both enzyme treated, and non-enzyme treated.

Description	Product Code
3% in Alsevers- Panel 1	PR144
3% in Alsevers- Panel 2	PR141
3% in Alsevers- Panel 1 enzyme treated	PR154
0.8% in CellStab-Panel 1	PR143
0.8% in CellStab-Panel 2	PR142
0.8% in CellMedia – Panel 1	PR163
0.8% in CellStab -Panel; 1 enzyme treated	PR153
0.8% in CellStab- Panel 2 enzyme treated	PR152
0.8% in CellMedia- Panel 1 enzyme treated	PR173
1.5% in LISP- Panel 1	PR146

Titration Cells (PR407)

This product is intended for use in titration studies (e.g., in antenatal samples). The product consists of two selected cells, in CellStab, providing heterozygous expression of: C, c, E, e, M, N, S, s, K, k, Fy^a, Fy^b, Jk^a and Jk^b.

Products for further investigations

Papain (PN090)

Red cells can be treated with papain and then used to test serum/plasma to enable identification of any 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 (PN161)

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.

DTT (PN221 0.2%, PN222 0.01%)

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 fetomaternal 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.

Description	Product Code
Weak antibody control – anti-Fy ^a	PN044
Weak antibody control – anti-c	PN042
Weak antibody control – 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.

Internal proficiency exercises (PN083)

IPEX (PN083) is available 6 times a year, usually consisting of 3 serum and 3 matching cell samples. The expected results for ABO and Rh typing, antibody screening and identification are emailed to a designated person.

At least one exercise per year is based on a transfusion reaction case.

To make this a true learning experience, exercises are accompanied by some CPD questions with answers and relevant references.

Projects, evaluations, validations and acceptance testing at NHSBT

Reagents – meeting your serology needs.

The advantages of working with NHSBT Reagents:

- Processes are developed and managed by highly experienced Red Cell Immunohaematology Biomedical Scientists and reagents manufacturers.
- Material will be evaluated using standard blood transfusion equipment including those supplied by the leading equipment manufacturers.
- Flow cytometry is used for selected tests.
- We have access to an extensive red cell inventory including rare types.
- We have access to a variety of plasmas containing varying strengths of antibodies.

Evaluation against:

- Standards.
- Guidelines.
- Common technical specifications.
- New techniques.
- New technologies.
- User specifications.

Choice	Support	Control
44 different products Red cell reagents Compatibility with commercial platforms Accessory solutions	Customer service centre	Quality EQA exercises Validation services Annual customer survey

Contact Information

Gary Cavanagh
Business Development Manager, Red Cell Immunohaematology
E-mail: gary.cavanagh@nhsbt.nhs.uk
Telephone: +44 (0) 7384915763

Michelle Weston RCI National Reagents Manager
E-mail: michelle.weston@nhsbt.nhs.uk
Telephone: +44 (0)151 268 7160

Reagents Customer Services
E-mail: reagents@nhsbt.nhs.uk
Telephone: 0151 268 7157

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