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Product code	Product Name	UDI-DI
PR051	Whole Blood Controls	5055232400017

Amendments from the previous version of these instructions for use are in purple text.

Intended use
For professional use as an IVD device for the control of automated blood grouping and antibody screening systems. This reagent can be used to give qualitative data to assure the effectiveness of each batch of laboratory test. The device is intended for QC of the automated system as a whole and not as a specific control for ABO grouping.

Principles of the examination method
The product has been designed to replicate a patient's sample for use in automated immunohaematology testing. Whole blood control samples should be tested on the analyser in the same way as patient samples.

Components
Whole blood controls consist of 2 vials, each vial is differentiated by a letter A or B.
These reagents are prepared from non-remunerated donor blood, are leucodepleted, washed and suspended in a preservative solution.
This product is supplied as red cells diluted to 33 ± 3% in human plasma, which has been diluted in Alsevers preservative.
Vial A will be group A, either Rh D positive or negative and K+ or K- and will contain either anti-D or anti-K.
Vial B will be group B, either Rh D positive or negative and K+ or K- and will contain either anti-D or anti-K. The supplied vials will contain anti-D and anti-K in each lot.
The product is supplied in 5mL volumes, to be used directly from the vial.

Special materials and Equipment required but not supplied
- Bio-Rad ID-System, Grifols DG Gel System or ORTHO ID-MTS consumables and equipment.
- Centrifuge.

Reagent Preparation
Centrifuge before use. Allow to reach required temperature for test to be performed.

Storage and shelf life after first opening
Store at 2-8ºC.
Once opened the device can be used until stated expiry date.
Do not use beyond the expiry date.
Immediately after use, the vial must be capped and placed back, upright, in the correct storage temperature.

Warnings and precautions

The donations used in this product are of human origin. They have been tested and found negative for the mandatory microbiological tests required by the UK Guidelines for Blood Transfusion Services during donation testing. No known test methods can offer assurances that products derived from human blood will not transmit infectious diseases. This device should be handled as clinical material. The device and any contaminated packaging should be disposed in accordance with local, state or national legislation.

For healthcare professional use only.

Cells must not be pooled by user.

Do not use if red cells appear contaminated, discoloured or haemolysed.

When used in accordance with the Instructions for Use and Good Laboratory Practices, there is limited potential for carryover.

This device is not provided sterile.

Do not use if the reagent vial is cracked or leaking.

Some loss of antigenic expression or antibody strength may occur during the stated shelf life. Since this loss cannot be predicted or controlled and is partly determined by the characteristics of individual blood donations or donors, the recommended conditions of storage and use must be rigidly applied.

Examination procedure

The product should be used according to user laboratory procedures and be tested as a patient sample.

For method of use in Bio-Rad ID system, Ortho BioVue or DG Gel System refer to the instructions for use of the technologies being used.

Suitability for use by other technologies cannot be guaranteed.

If controls set up with the batch of tests fail to give required results, then all tests must be repeated.

Interpretation of results

The strength of reaction should be graded in accordance with user laboratory protocol. The pattern of reactivity obtained should be reviewed against the profile provided.

This product is designed as a control and so only provides an indication that the system is detecting types as given on the profile.

Performance characteristics

To confirm the antigen profile, and rule out cross-reactivity, each cell is tested against 2 examples of phenotyping antisera for each specificity. Antigen strength is tested by presence or absence of antigens described by allelic genes.

The plasma has been tested using a panel of red cells which bear the following antigens: Le^a, Le^b, K, Kp^a, P1, Cw, M, N, S, s, Lu^a, Jk^a, Jk^b, Fy^a, Fy^b to assure the absence of other blood group antibodies. Negative reactions with this panel also exclude the presence of antibodies to antigens having a prevalence of greater than 99%.

Limitations of the examination procedure

Improper techniques may invalidate the results obtained with this product.

Users are advised to validate the reagent's suitability before using with alternative techniques.

False positive or false negative results can occur due to contamination, improper storage, incubation time or temperature, improper or excessive centrifugation or deviation from the recommended technique.

Exogenous interference is possible by antibodies to low incidence blood group antigens which may occur as contaminants and may, on rare occasions, give rise to false positive results.

Literature references

Directive 98/79/EC on In vitro diagnostic medical devices.
Guidelines for the Blood Transfusion Services in the UK.
British Society for Haematology Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories.

Note – Any serious incident that has occurred in relation to this product should be reported to the manufacturer and the competent authority in which the user and/or the patient is established.

EC REP
Quality First International OÜ, Laki 30,12915 Tallinn, Estonia.

Symbols used on NHSBT Reagents labels.

Note - not all symbols listed are applicable for this product - please refer to product labels.

Detail	Label details
Batch code symbol	LOT
Use by date symbol	
Expiry date format	YYYY.MM.DD
In Vitro Diagnostic medical device symbol	IVD
Instructions for use symbol (with website - electronic IFU)	 blood.co.uk/reagents
Negative control symbol	CONTROL –
Positive control symbol	CONTROL +
EC Rep symbol	EC REP

Detail	Label details
2-8°C temperature range symbol	
Below -20°C symbol	
CE Mark symbol	CE
UKCA symbol	UK CA
Manufacturer's symbol	
Keep Away from Sunlight symbol	
Contains human blood or plasma derivatives symbol	
Unique Device Identifier symbol	UDI

Lot number Format

NHBST Reagents product lot numbers are in the following format:

NAAA MXXX or RAAA MXXX

N Non-Red cell or R Red cell

AAA Product identifier from product code

M Reagent Manufacturing Unit - main batch = 3
And sub-batch identifier - 4, 5, 6 .... etc for sub batch

XXX Lot number