All the products manufactured and commercialised by Bio-Rad are under complete quality system starting from reception of raw material to the final commercialisation of the product. Each lot is submitted to a quality control and only is released on the market when conforming to the acceptance criteria. The records relating to production and control of each single lot are kept within our company.
I - USE AND PRINCIPLE OF THE TEST
This reagent is strictly reserved for professional and in vitro diagnostic use. Designed for direct crossmatch test in one-step enzymatic technique, the test combines the principles of agglutination and gel filtration. The reaction is obtained and read after centrifuging specially designed microtubes containing neutral gel. The red blood cell suspension, the plasma or serum and the reagent ScanBrom are distributed into the microtubes and the microtubes centrifuged after an incubation period. Non-agglutinated red blood cells are collected at the bottom of the microtube while the agglutinates are dispersed throughout the length of the gel, depending upon their size. Their position in the gel determines the intensity of the reaction.

II - CHARACTERISTICS OF THE REAGENT
ScanBrom is a bromelain solution in liquid form, ready for use, stable and sterile, obtained from a Comosus pineapple extract. Bromelain is a proteolytic enzyme which modifies the red blood cell antigens in such a way as to increase the reactivity of some antigen-antibody pairs, particularly for RH, P, I, JK, LE systems. On the other hand, the antigens belonging to the MNS, FY, YT, CH/RG, XG, IN and GE systems are destroyed or altered by proteolytic enzymes. The reagent contain sodium azide (< 0.1%) as preservative. Sodium azide may react with laboratory plumbing into copper or lead azides. Such azides are explosive. To prevent azide build-up, flush the pipes with a large quantity of water if solutions containing azide are thrown in the sink after inactivation. The product code and volume are stated on the box label.

III - STORAGE – SHELF LIFE
Store the reagent at +2°C - +8°C. Do not freeze. The expiry date and storage conditions are stated on the label of each vial. The reagent can be used 4 weeks after opening, subject to correct storage conditions, aiming to avoid any contamination. Do not use reagent in case of change in appearance (e.g.: cloudiness, sediment).
IV - WARNINGS AND PRECAUTIONS
The reliability of the results depends on correct adherence to the following Good Laboratory Practices:

- Do not use the reagents after the expiration date indicated on the label.
- Do not use cards showing signs of drying, bubbles, a damaged or partially removed seal strip.

**It is essential to take precautions in order not to provoke between-microtube contamination, particularly during the distribution steps.**

- Use a different tip for each sample.
- Check that the pipettes and other apparatus are working correctly and check their precision.
- Wear gloves and safety glasses when handling the reagents and samples.
- Never pipette directly by mouth.
- Avoid splashing. In the event of splashes, clean with 12°C1 bleach (Javel water) diluted 1:10 and wipe with absorbent paper. The materials used for cleaning are to be discarded in the contaminated waste container.
- Consumables and products which have been in contact with either samples or reagents which contain material of human origin, must be discarded after they have been decontaminated.
- The safety datasheets are available on request.

V - SAMPLING AND SAMPLE PROCESSING
Draw the blood aseptically into a tube without or with anticoagulant (EDTA). Conduct the test as soon as possible after sampling. Samples that cannot be analysed rapidly should be stored between +2°C and +8°C and tested within 48 hours. Under no circumstance should haemolysis be visible. The blood of the donor is obtained from a segment of the tubing of the blood bag (CPD).

Do not heat the samples.

VI - METHOD
Equipment supplied
- ScanBrom

Material required but not provided
- ScanLiss : red blood cell suspension medium
  86441 ScanLiss 100 ml
  86442 ScanLiss 500 ml
- ScanGel NEUTRAL
- IH QC : Blood group serology control
  86745 IH QC 4 x 6 ml
- Incubator : ScanGel Incubator
• Centrifuge: ScanGel Centrifuge
• Automatic or semi-automatic pipettes
• Pipette tips
• Disposable tubes
• Container for wastes associated with a biological risk
• Bleach (Javel water)
• Latex gloves
• Absorbent paper
• Safety glasses

Controls
• Positive control (known serum, containing at least one antibody detectable in the recommended technique) and negative control (known serum, containing no antibody). IH QC: Blood group serology control.

Procedure
**Strictly comply with the procedure.**
Allow all the reagents to reach room temperature before use.
Separate the serum or plasma from the red blood cells of the sample by centrifuging (2000 g x 2 minutes).
When the blood is drawn without anticoagulant, centrifuge the serum a second time at 1500 g for 10 minutes.

a) Preparation of donor red blood cells suspension
• Transfer 1 ml of ScanLiss to a labelled disposable tube.
• Add 10 µl of red blood cell pellet of the donor
• Mix. The suspension of red blood cells is ready for use.

b) Method
1. Label each card or part of card with the receiver name or number and with the corresponding donor’s number(s).
   Withdraw the entire aluminium strip from the card.
   Resuspend the red blood cells before use.
2. Transfer 50 µl of each red blood cell suspension as prepared in a) into the well of the appropriate microtubes.
3. **Immediately** add 25 µl of receiver plasma or serum into the well of the appropriate microtubes. Under no circumstance must the interval between red blood cells suspensions transfer and plasma or serum transfer exceed 10 minutes.
4. Add 25 µl of ScanBrom into the well of each microtube.
5. Incubate **immediately** at 37°C for 15 minutes in ScanGel Incubator.
6. Centrifuge immediately 10 minutes in ScanGel Centrifuge. Under no circumstance must the interval between the end of the incubation and the start of the centrifugation exceed 10 minutes.

7. Read the reactions.

VII - RESULTS AND INTERPRETATION

- Agglutinates (on the surface of, or dispersed through, the gel) and/or an haemolysis in the microtube constitutes a positive result.
- A compact red blood cell button at the bottom of the microtube and the absence of haemolysis corresponds to a negative result.

<table>
<thead>
<tr>
<th>Positive result</th>
<th>Negative result</th>
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- The results are validated only if the positive and negative controls give the expected results.
- A positive result (agglutination and/or haemolysis) in one of the microtubes demonstrates an incompatibility between the receiver serum or plasma and the donor red blood cells.

VIII - PERFORMANCE

The performance evaluation gave concordant results with the reagent used as a reference.

Each result has been compared with the one obtained in gel filtration technique. Some incompatibilities were not highlighted by this only test but, on the other hand, were highlighted by the indirect antiglobulin test in ScanGel technique. Moreover, some antigens, such as MNS1 (M), MNS2 (N), MNS3 (S), FY1 (Fya), FY2 (Fyb) and XG1 (Xgα) are destroyed or altered when red blood cells are treated with proteolytic enzyme. Thus, enzymatic technique can not be used as the only technique for crossmatch test.

The reproducibility of the application was tested and showed good performance in both intra and inter tests.

LIMITS

Abnormal results may be caused by:
- bacterial or chemical contamination of the serum, plasma, red blood cells or equipment.
- patient medication or disease yielding a cross-reaction.
- use of a red blood cell suspension medium other than that recommended.
- a red blood cell preparation different to that recommended.
- incomplete resuspension of the red blood cells.
- sample or red blood cell haemolysis.
• the presence of fibrin (compact cell button at the bottom of the microtube together with a fine pink band at the top of the gel made up of red blood cells retained by the fibrin residues).
• a degradation of the enzymatic activity of bromelain (no compliance of storage conditions).
• between-microtube contamination.
• use of other procedure than the one described above.

IX - LITERATURE
CE marking (European directive 98/79/CE on in vitro diagnostic medical devices)
- Marquage CE (Directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro)
- Marco CE (Directiva europea 98/79/CE sobre productos sanitarios para diagnóstico in vitro)
- EG Markierung (Europäische Richtlinie 98/79/EG über In-vitro-Diagnostika)
- Marchiatura CE (Direttiva europea 98/79/CE relativa ai dispositivi medico-diagnostici in vitro)
- Marcação CE (Directiva europeia 98/79/CE relativa aos dispositivos médicos de diagnóstico in vitro)
- CE-märkning (Europa direktiv 98/79/EG om medicintekniska produkter för in-vitro-diagnostik)
- CE-mærkningen (Europa direktiv 98/79/EF om medicinsk udstyr til in-vitro-diagnostik)

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