

Medcaptain Blood Grouping Gel Systems

Bromelin Solution

REF No: RCBS10, RCBS50

CE1434

IVD

INTENDED USE

Bromelin Solution is used for preparing suspensions of red cells for blood grouping and as an additive for enzyme tests with untreated red cells for antibody detection.

INTRODUCTION

Enzymes often used in blood group serology are the proteases bromelin, ficin, and papain. Proteases also remove sialic acid residues attached to peptides. Enzymes are more effective at increasing the ability of certain antibodies to promote agglutination. Enzyme treated cells are used in antibody screening and in antibody identification procedures.

REAGENT

Bromelin Solution: 10 and 50 ml bottles. Ready to use. Contains 0,1% sodium azide as preservative.

MATERIAL REQUIRED BUT NOT PROVIDED

- Pipettes.
- Disposable pipette tips.
- Test tubes.
- Dispenser
- Medcaptain Automated Gel Systems.

STORAGE CONDITIONS AND STABILITY

The reagent should be stored at 2°C - 8°C.

The reagent is stable until the expiry date stated on the product label.

Once opened the shelf life of the reagent vial is as described on the reagent vial label if stored 2-8°C. Prolonged storage at temperatures outside may result in accelerated loss of reagent reactivity.

Do not freeze or expose the reagent to elevated temperatures. After usage immediately replace the reagent vial back to 2-8°C.

PRECAUTIONS AND WARNINGS

- This reagent kit is for in vitro diagnosis only.
- Do not use if turbid.
- Do not dilute
- This reagent kit is for professional use only.
- The reagent contains sodium azide 0.1% as preservative.
- Avoid contact with skin and mucosa.
- Do not use damaged or leaking reagents.
- Do not use the reagents past the expiration date.
- Do not use the reagents if a precipitate is present.
- All kit components and specimens should be regarded as potential hazards to health. It should be used and discarded according to your own laboratory's safety procedures.

SAMPLE COLLECTION

Fresh red blood cells are preferred for testing . Use the red blood cells collected with anticoagulants for determination of the antigens of the ABO/Rh system .

Red blood cells collected in ACD, CPD, SAGM and PAGGSM can also be used until the expiry date indicated on the label of the bag at 2-8 °C.

Fibrin residues may interfere with the reaction pattern.

PREPARATION OF BLOOD

Do not use haemolysed, cloudy or contaminated samples or those containing clots

5 % red blood cell suspension(for blood grouping) :

- 1- Bring Bromelin solution to reach room temperature before use
- 2- Dispense 0,5 mL of Bromelin solution into a clean tube.
- 3- Add 50 µL of whole blood or 25 µL of packed cells to the diluent and mix gently.

Antibody screening, Crossmatch:

Bring Bromelin solution to reach room temperature before use.

After pipetting of the 0,8% red cell suspension and the serum or plasma sample to the appropriate microtubes of an REDCELL gel card corresponding to the required test procedure, add 25 µL of to Bromelin solution each microtube.

Continue with the other procedures








LIMITATIONS

- Stored blood may give weaker reactions than fresh blood.
- Bacterial or other contamination of materials used can cause false positive or false negative results
- Hemolysed samples may interfere the final interpretation of results.
- Over-treatment of red cells by enzyme may result in unwanted positive reactions due to the exposure of crypt-antigens.
- Proteolytic enzymes modify red blood cell antigens and suppress such as M, N, S, Fya and Fyb.

PERFORMANCE CHARACTERISTICS

Bromelin solution was evaluated with 240 samples (from donors, patients). The evaluation demonstrated 99.1 % specificity and 100% sensitivity of the reagent versus the expected results with Cross match, DAT, Antibody screening.

Label symbols

	Batch code
	Expiry date
	Storage temperature
	Consult instructions for use
	In vitro diagnostic medical device
	Product code
	Manufacturer

BIBLIOGRAPHY

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- 2-Geoff Daniels, Imelda Bromilow, Essential Guide to Blood Groups , Blackwell Publications 2010
- 3-Harvey G. Klein MD, David J. Anstee ,Mollison's Blood Transfusion in Clinical Medicine 11TH EDITION Blackwell Publishing Ltd
- 4-Michael F. Murphy , Derwood H. Pamphilon , Practical Transfusion Medicine Third Edition 2009 Blackwell Publishing Ltd
- 5-Neil D. Avent and Marion E. Reid , The Rh blood group system: Blood 2000 95: 375-387
- 6- Christopher D. Hillyer ... BLOOD BANKING AND TRANSFUSION MEDICINE, Second Edition, Churchill Livingstone 2007
- 7-Lapierre Y., Rigal D., Adam J. et al.: The gel test; A new way to detect red cell antigen-antibody reactions. Transfusion 1990; 30: 109 –113.
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4- Incubate the red cell suspension for 10 minutes at room temperature.
Use within 20 minutes after incubation

Products : Bromelin Solution
10 ml REF RCBS10
50 ml REF RCBS50

Manufacturer:
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