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CE

Instruction for Use

Rev. 002 /2022-02

Product name	Product-Code
Bromelin solution 10 ml	37110

IN VITRO DIAGNOSTIC

SUMMARY
The effect of bromelin is based on a reduction in the charge of erythrocyte and a separation of polypeptide chains that protrude from the erythrocyte membrane. The enzymatic effect of bromelin increases the antigen-antibody reaction in blood group serology, especially in the Rhesus, Kidd, Lewis, Vel, and H systems. Bromelin test can also be useful for the detection of weak isoagglutinins of the AB0 system.
However, the use of bromelin can destroy various blood group antigens (e.g. MNSs, Duffy, Xg, Pr and T) or reduce reactivity.

PRINCIPLE
Enhancer medium for use in tube testing.
Bromelin solution can be used if the agglutinate is very weak or doubtful.
The user must determine suitability of the reagent for use in other techniques. The product is intended for diagnostic laboratory use only.

PRODUCTINFORMATION
Bromelin is a preserved, stable enzyme solution that is isolated from pineapple and manufactured according to the process and working instructions of our QM system. As a preservative, 0.01% neomycin sulfate is added to the reagent. This reagent is ready for use and is to be used without additiva (Albumin, LISS, etc.) or dilution as supplied

STORAGE
Reagent vials should be stored at 2°C-8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

SAMPLE COLLECTION
The red blood cells to be examined are collected, prepared and stored as specified in the instructions for use of the test reagents or cell panels. Serum must be used to determine antibodies in the tube test.

PRECAUTIONS
1. This reagent is intended for in vitro diagnostic use only.
2. Do not use the reagent past the expiration date (See vial label)
3. Do not use the reagent if a precipitate is present.
4. Protective clothing should be worn when handling the reagent, such as disposable gloves and a laboratory coat.
5. This reagent is only to be used by properly trained and qualified personnel.
6. The reagent is not intended for self-use.
7. If a vial is cracked or leaking, discard content immediately.
8. No hemolytic samples may be used.
9. The reagent has been filtered through a 0.2 µm mambrane to reduce bio-burden.
10. Once a vial has been opened the content should remain viable up until the expiry dateas long as there is no marked turbidity, which can indicate reagent deterioration or contamination.

DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES
For information on disposal of the reagent and decontamination of a spillage site see Material Safety Data Sheets, available on request at CE-Immundiagnostika GmbH.

CONTROLS AND ADVICE
Any test using patient or donor cells and serum should be controlled. In each test series, a bromelin-control reagent with a mixture of weak Rhesus antibodies (which react positively with all erythrocytes) should be tested to test enzyme activity.

REAGENTS AND MATERIALS REQUIRED
- Donor- or patients samples or testcells, donor- or patients serum or commercial reagent red blood cells
- Isotonic saline solution
- Glass test tubes and test tube centrifuge
- Test tube racks
- Calibrated centrifuge

RECOMMENDED METHODS: TUBETEST
1. Wash blood twice and prepare a 2-3% erythrozytesuspension in 0,9% isotonic saline.
2. a) 1-2 drops proband serum to be tested into a labelled tube, add same amount test erythrocytes and mix well. Or
   b) 1-2 drops specific antiserum into a labelled tube, add same amount proband serum and mix well.
3. Add 1 drop Bromelin solution and mix well.
4. Inkubate 15 minutes at roomtemperature. If the detection of cold active antibodies is not desired, incubation at 37°C is recommended.
5. Centrifugation 1 minute at 400g (ca. 1500 rpm) or for a suitable alternative time and force.
6. Gently resuspend red cell button and read macroscopically for agglutination.
7. Documentation of results.

The test can be stopped here or a Coombs test can be performed afterwards. The instruction for use of the AHG reagent (AHG polyspez.-rabbit) must be observed.

INTERPRETATION OF TEST RESULTS
The specified test method is based on the principle of direct haemagglutination. After the addition of erythrocytes (proband or test erythrocytes) and bromelin to the serum (proband or test serum), a specific antigen-antibody reaction occurs only if an antibody and the corresponding antigen are present on the erythrocytes .
1. **Positive:** The agglutination of the erythrocytes indicates the presence of the corresponding antigen on the erythrocytes. Please observe the limits of the test method (see below).
2. **Negative:** no agglutination indicates the absence of the corresponding antigen on the erythrocytes. Please observe the limits of the test method (see below).

LIMITATIONS
1. blood should be not older than 4 days, otherwise it may lead to weaker results.
2. Due to the variability of antigen expression, the cells of some phenotypes may react weaker than the positive control used for the test.
3. False positive or false negative results can be caused by:
   • Contamination of the material to be tested
   • Incorrect storage, incorrect erythrocyte concentration, incorrect incubation time, incorrect temperature
   • Incorrect centrifugation
   • Deviations from the recommended methods

STABILITY OF THE REACTIONS
1. Tubetests must be read immediately after centrifugation.
2. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

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SPECIFIC PERFORMANCE CHARAKTERISTICS

1. Bromelin solution tested with the recommended method before release.
2. Each batch is tested before release against antigen-positive erythrocytes suitable for this method to ensure good reactivity.
3. Each batch is tested for efficacy before release with bromelin control reagent.
4. In quality control, erythrocytes washed twice in 0.9% saline are used.

DISCLAIMER

1. The user is responsible for the performance of the reagent by any method other than those mentioned in the Recommended Techniques.
2. Any deviations from the method recommended should be validated prior to use.

BIBLIOGRAPHY

1. Issitt PD, Anstee DJ. Applied blood group serology. 4th ed. Durham, NC Montgomery Scientific Publication, 1998
2. Brecher ME. Ed. Technical manual 14th ed. Bethesda MD. American Association of Blood Banks, 2002.
3. Metaxas-Bühler M, Blutgruppen und Transfusion, Verlag Hans Huber, 1984

TABLE OF SYMBOLS

LOT	Batchnumber	IVD	In-vitro Diagnosticum
REF	Product-Code		Storage at +2 - +8°C
	Expiry date		Manufacturer
	Instruction for use inside		

Article numbers

REF	Article	Amount
37110	Bromelin solution	1 x 1 x 10 ml 5 x 1 x 10 ml 10 x 1 x 10 ml 50 x 1 x 10 ml