

# Bromelin for Erytype

FOR IN-VITRO DIAGNOSTIC USE  
Reagent for Tango<sup>®</sup> optimo

## Package size

[REF] 806210100 [VOL] 10 x 10 mL Bromelin for Erytype

## Intended Use

Bromelin for Erytype is intended for use as a diluent in the preparation of red blood cell suspensions for AB0/Rh, Rh phenotyping and Kell typing with Erytype S and the TANGO<sup>®</sup> optimo.

## Summary and Principle

Red blood cells are negatively charged due to sialic acid present on the membrane. This negative charge causes repulsion between red blood cells when suspended in a saline medium. The addition of bromelin (a proteolytic enzyme) to the test system liberates sialic acid residues from the red blood cell, thereby lowering the zeta potential.<sup>1</sup> Lowering the zeta potential brings the red blood cells closer together.

## Reagent

Bromelin for Erytype is supplied as a 1% solution in a 10 mL bottle. The solution is adjusted to a final pH of 3.75-4.05. The operator must make a 1:20 working dilution of the bromelin solution daily with isotonic saline (unbuffered).

Preservatives: 0.005% Gentamycin, 0.05% Streptomycin, 0.05% Penicillin

## Precautions

- For In-vitro diagnostic use.
- Store at 2 to 8°C.
- Do not use beyond the expiration date on the stock solution bottle.
- Do not exceed the 24-hour expiration for the working solution.
- Do not use phosphate buffered saline to prepare the 1:20 dilution.
- The antibiotic mixture in the stock vial may cause turbidity and intense odor. The turbidity has no influence on the enzyme activity.
- Do not freeze.
- Caution: This product contains Natural Rubber Latex Which May Cause Allergic Reactions.
- Warning: Bromelin is a proteolytic enzyme that may cause severe irritation to the mucosal membranes. Avoid inhalation or skin contact with stock and working solutions. Flush areas of exposure well with running water.**

## Specimen Collection and Preparation

### Erytype S ABD+Rev. A, B

EDTA anticoagulated whole blood collected following general blood sampling guidelines are acceptable.

The specimen should be tested as soon as possible after collection. If testing is delayed, EDTA anticoagulated specimens should be stored at 2 to 8°C.

Blood specimens exhibiting gross hemolysis or contamination should not be used.

Stored samples should be allowed to reach room temperature prior to testing and may be tested for up to seven days after collection.

### Erytype S Rh + K Type

EDTA or citrate anticoagulated whole blood collected following general blood sampling guidelines are acceptable.

The specimen should be tested as soon as possible after collection. If testing is delayed, EDTA anticoagulated specimens should be stored at 2 to 8°C. Donor segments taken from the original unit of whole blood or packed red blood cells are suitable for testing. Donor segments are suitable for testing through the expiration date of the original unit as long as they have been stored at 1 to 6°C. The red blood cells from the segment must be prepared for testing per the requirements in the TANGO<sup>®</sup> optimo.

Blood specimens exhibiting gross hemolysis or contamination should not be used.

Stored samples should be allowed to reach room temperature prior to testing and may be tested for up to seven days after collection. A distinct separation between plasma and red blood cells must be visible for testing. Samples may be centrifuged or allowed to settle.

### Erytype S AB0 Donor and Erytype S Rh Donor

Donor segments taken from the original unit of whole blood or packed red blood cells are suitable for testing. Donor segments are suitable for testing through the expiration date of the original unit as long as they have been stored at 1 to 6°C. The red blood cells from the segment must be prepared for testing per the requirements in the TANGO<sup>®</sup> optimo.

## Materials

### Materials Supplied:

- Bromelin for Erytype

### Material required but not provided:

- Centrifuge
- Isotonic saline
- TANGO<sup>®</sup> optimo [REF] 848900010
- Anticoagulated Samples or Donor Segments

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- Erytype S AB0 Donor [REF] 806130100, Rh Donor [REF] 806190100, ABD+Rev.A, B [REF] 806127100 or Rh+K Type [REF] 806195100
- 12x75mm sample tubes.
- Pipettes to make 1:20 working dilution of Bromelin.

## Test Procedure

### Preparation

- Prepare a 1:20 working dilution of Bromelin using isotonic saline for use on the TANGO<sup>®</sup> optimo. The 1:20 concentration of the working solution can be prepared by adding 1 mL of Bromelin stock solution to 19 mL of Isotonic Saline. **Once prepared, the working dilution is stable for 24 hours.**

**Note: Do not use buffered saline to prepare the working solution of Bromelin for Erytype.**

- Load Bromelin for Erytype as instructed in the TANGO<sup>®</sup> optimo.

## Quality Control

A series of quality control samples must be run each day before testing or according to local requirements to ensure that the reagents, antisera and the TANGO<sup>®</sup> optimo Blood Bank Analyzer are functioning properly.

Additionally, controls should be run whenever:

- A lot number changes (plate, reagent).
- A new bottle or preparation is placed on the system.
- Following service or repair of the analyzer.

Controls may be selected from previously tested blood samples. Controls should be selected from samples that are less than 7 days old. Clotted, grossly hemolyzed, or grossly lipemic samples should not be used for quality control samples.

Control samples should be selected to verify positive and negative reactions with every reagent. The following example may be used for AB0/Rh quality control testing. Other configurations of AB0 and Rh types are necessary (e.g. anti- C, - c, -E, -e, -K) and acceptable as long as there is a positive and negative control for each reagent

Group 0 Neg  
Group AB Pos  
Group A Neg  
Group 0 Pos

## Interpretation

The tests are considered valid if a positive and negative result exists for each antisera/ reagent tested. A positive result is not required for the Negative Control. If the controls do not give expected results, you must determine the cause for the failed QC.

Follow institutional SOP for repeat testing of QC samples, repeat testing of patient/donor samples and documentation of QC results and corrective action if required.

## Limitations of the Procedure

- Violent shaking may destroy or reduce enzyme activity.
- Exposure to temperatures greater than 28°C may reduce enzyme activity.

## Specific Performance Characteristics

Testing is performed in accordance with FDA recommended methods.

The final release testing is performed according to the product specific SOPs. Each lot of Biotest Reagent is tested in the Quality control by package insert method to insure suitable reactivity.

For the product performance it is necessary to adhere to the recommended method in the instructions for use.

When used as directed, Bromelin for Erytype provides enhanced agglutinability of AB0, Rh and Kell reactions.

For Technical Support or further product information, contact Biotest Diagnostics Corporation at 800-522-0090.

## Glossary of Symbols

Symbol	Definition	Symbol	Definition
[LOT]	Batch Code	[IVD]	In vitro diagnostic medical device
⚠	Caution, consult accompanying documents	📖	Consult instructions for use.
🏭	Manufacturer	🕒	Use by YYYY-MM-DD
⚖	Contains sufficient quantity for <n> tests.	[REF]	Catalog number
🌡	Temperature limitation		

## Bibliography

- Issitt, Peter D. and Issitt, Charla H. Applied Blood Group Serology. Oxnard, CA: Spectra Biologicals, 1979.



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**FOR REFERENCE USE ONLY: DO NOT USE IN PLACE  
of package inserts provided with each product.**