Bromelin for Erytype®, FOR IN-VITRO DIAGNOSTIC USE
Enzyme Reagent for TANGO® instruments
Rx only

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 ABO/Rh, Rh phenotyping and Kell (KEL1) typing with Erytype® S on TANGO® instruments.

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. 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 operator must make a 1:20 working dilution of the bromelin solution daily with isotonic saline (unbuffered). Preservatives: 0.005% Gentamicin, 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.
• 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
For product specific sample handling instructions, refer to the Specimen Collection section in the respective instructions for use for Bio-Rad products Erytype® S ABO+Rev. A,B, Erytype® S Rh+K Type, Erytype® S ABO Confirm and Erytype® S RhD Confirm.

Materials
Materials Supplied:
• Bromelin for Erytype®

Material required but not provided:
• Centrifuge
• Isotonic saline
• Deionized water
• TANGO® optimo REF: 848900010 or TANGO® infinity® REF: 850000010
• Anticoagulated Samples or Donor Segments
• Erytype® S ABO Confirm REF: 806130100, Erytype® S RhD Confirm REF: 806190100, Erytype® S ABD+Rev. A,B REF: 806127100 or Erytype® S Rh+K Type REF: 806195100
• 12 x 75mm 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® instruments. 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 respective instrument User Manual.

Quality Control
Please refer to the specific instrument User Manual and the Erytype® S product used for testing for recommended instrument quality control.

Interpretation
Please refer to the respective Erytype® S instructions for use or the instrument User Manual.

Limitations
• 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. As part of the release testing, each lot of Bio-Rad Reagent is tested according to the 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 agglutination of ABO, Rh and Kell reactions.

For Technical Support or further product information, contact Bio-Rad Laboratories Inc., at 800-224-6723.

Note
Used test materials must be discarded as hazardous material. Manage waste according to local, state and national regulations.

Glossary of Symbols

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<th>Symbol</th>
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<tr>
<td>®</td>
<td>In vitro diagnostic medical device</td>
<td>[LOT]</td>
<td>Batch Code</td>
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<td>□</td>
<td>Consult instructions for use.</td>
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Bibliography

Key: Underline = Addition of changes   ◄ = Deletion of text