

**ERYBANK**®

Rh-hr CONTROL FOR SLIDE AND TUBE TESTS

SUMMARY

To confirm, that the Rh-hr determination in blood typing is a specific reaction between the test reagent and the test cells, a negative control of each sample is strongly recommended.

PRESENTATION

REF	102210005
ERYBANK® Rh-hr Control	5 ml
Pack insert	1

REAGENT

ERYBANK® Rh-hr Control contains the same ingredients as the ERYCLONE® Anti-D and RHOFINAL® Anti-D reagents without the specific antibodies. A negative test result ensures a specific reactivity with ERYCLONE® Anti-D and RHOFINAL® Anti-D blood typing reagents. Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagents at 2-8 °C. **DO NOT FREEZE.**
2. The shelf life of the reagent is limited by the expiry date. Once opened the shelf life is as described on the reagent vial label provided it is not contaminated.

PRINCIPLE

ERYBANK® Rh-hr Control serves as a negative control parallel to Anti-D testing using ERYCLONE® Anti-D and RHOFINAL® Anti-D. The result should be negative. A positive result demonstrates, that there is a cross reaction between reagent components and the cells without specific antibody. In this case the test result with the specific ERYCLONE® Anti-D and RHOFINAL® Anti-D reagent is not utilizable and demands a retesting.

NOTE

1. In Vitro Diagnostic reagent for laboratory and professional use. Not for medicinal use.
2. The reagent contains sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
4. ERYBANK® reagents are not from human source, hence contamination due to HBsAg and HIV is practically excluded.

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection by approved techniques. sample should be stored at 2-8°C if not tested immediately. For optimal results freshly collected sample should be used. Anticoagulants like EDTA, CPDA and citrate can be used. Do not use haemolysed sample.

ADDITIONAL MATERIAL REQUIRED FOR SLIDE AND TUBE TESTS

Glass slides (60 x 85mm), Test tubes (12 x 75mm), Pasteur pipettes, Isotonic saline, Centrifuge, Timer, Mixing sticks.

TEST PROCEDURE

All materials should be at room temperature before testing.

Slide Test

1. Place one drop of ERYBANK® Rh-hr Control using the reagent vial dropper, separately on a glass slide.
2. Add 50 µl of whole blood.
3. Mix well with a mixing stick uniformly over an area of approximately 2.5 cm².
4. Rock the slide gently back and forth.
5. Observe for agglutination macroscopically at the end of 2 min.

Tube Test

1. Prepare a 3-5% suspension of the red cells to be tested in isotonic saline.
2. Place one drop of ERYBANK® Rh-hr Control, using the reagent vial dropper, into a labelled test tube.

3. Pipette 50 µl of the cell suspension into the test tube and mix well.
4. Centrifuge 1 min (125 g) or 20 s (1000 g).
5. Gently resuspend the cell button, observing for agglutination macroscopically.

INTERPRETATION OF RESULTS

Slide and Tube Tests

No agglutination is a negative test result and indicates the correct reaction between ERYCLONE® Anti-D and RHOFINAL® Anti-D monoclonal antibodies and red cells. Agglutination is a positive test result and indicates an unspecific reaction between monoclonal reagent medium and red cells. Result of Rh-hr typing is invalid. Do not interpret peripheral drying or fibrin strands as agglutination.

REMARKS

1. As undercentrifugation and overcentrifugation could lead to erroneous results, it is recommended that each laboratory calibrates its own equipment and determine the time required for achieving the desired results.
2. After usage the reagents should be immediately recapped and replaced to 2-8 °C storage.
3. In case the ERYBANK® Rh-hr Control shows a positive reaction, a direct antiglobulin test should be carried out.
4. Test should be repeated with washed test cells in cases of rouleaux formation caused by atypical plasma proteins.
5. ERYBANK® Rh-hr Control can be used with ERYCLONE® Anti-D and RHOFINAL® Anti-D and similar ERYSCREEN® range of products.

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

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4. Technical Manual American Association of Blood Bank, Ninth Edition, 1985.127-153.
5. Data on file: Tulip Diagnostics (P) Ltd.

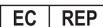
SYMBOL KEYS

 Temperature limitation	 Manufacturer	 Batch Number/ Lot Number	 This side up
 Use by	 Consult Instructions for use	 Description of reagent	
 Date of Manufacture	 Catalogue Number	 In vitro Diagnostic Medical Device	Authorised Representative in the European Community



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