RH-hr CONTROL
FOR SLIDE AND TUBE TESTS

SUMMARY
Rh-hr antisera/antibodies are fortified with Bovine Serum Albumin to enhance the reactivity of human blood typing antibodies in direct agglutination tests or indirect antiglobulin tests.

IgG antibodies, especially those of Rh specificities, will agglutinate red cells if the effective electrical charges on the cells (ZETA potential) is carefully adjusted by addition of colloids, salts and stabilizers.

To confirm that the Rh determination carried out on the test red cells is a specific reaction between the test serum/antibody and the Rh antigen, negative control of each Rh determination is strongly recommended.

REAGENT
ERYBANK® Rh-hr control is precisely matched to the composition of the ERYCLONE® Anti D; However it does not contain IgG class of antibodies with Rh specificity.
ERYBANK® Rh-hr control mimics exactly the reaction milieu of ERYCLONE® Anti D reagent.
Each batch of the reagent undergoes rigorous quality control at various stages of manufacture for its specificity and performance.

REAGENT STORAGE AND STABILITY
1. Store the reagent at 2 - 8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

PRINCIPLE
Positive reactions with ERYBANK® Rh-hr control are due to:
1. Rouleaux formation because of large quantities of plasma proteins.
2. Cold autoantibodies.
3. Warm autoantibodies.

Negative reactions with ERYBANK® Rh-hr control suggests a specific reaction between Rh specific antibody and the Rh antigen.

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.

TEST PROCEDURE
Slide Test and Tube Test
Procedures as mentioned on ERYCLONE® Anti D reagent package insert must be strictly followed.
Procedures as mentioned on ERYCLONE® Anti Human Globulin reagent package insert must be strictly followed.

INTERPRETATION OF RESULTS
1. No agglutination of the red blood cells: A negative result with the Rh-hr control using slide and/or tube test method confirms that Rh determination of the same blood sample, with the same procedure, is a specific reaction between the test serum and the Rh antigen.
2. Agglutination of the red blood cells: A positive result with the Rh-hr control using slide and/or tube test method may indicate that the Rh determination of the same blood sample, with the same method is not a specific reaction between the test serum and the Rh antigen.

REMARKS
1. In case the Rh-hr control shows a positive reaction, a direct coombs test should be carried out.
2. A positive direct coombs test may be due to warm antibodies indicating in vivo sensitisation of the cells with antibodies.

3. A negative direct coombs test may indicate rouleaux formation or presence of cold autoantibodies (interference by plasma or serum components).

4. It is recommended that after a positive direct coombs test, the Rh testing should be carried out using a complete saline reacting Rh testing reagent, such as RHOFINAL® Anti-D (IgM + IgG).

**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**


5. Data on file: Tulip Diagnostics (P) Ltd.