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AGTROL®

STARTER PACK FOR PREPARING COOMBS CONTROL CELLS

SUMMARY
Anti-human globulin reagent is used in blood group serology for performing compatibility testing, antibody screening, antibody detection and detection of D^{u} red cell type. Usage of Coombs control cells is advocated for functional validation of anti-human globulin reagent and procedural validation of tests employing anti-human globulin reagent.

PRESENTATION

REF	**10252010**
Pack Size	**10 ml**

REAGENT
AGTROL® starter pack for preparing Coombs control cells contains,
1. Ready to use, standardized prediluted Anti-D (IgG) monoclonal antibody reagent.
2. Red blood cell preserving solution for serological applications.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its performance characteristics.

REAGENT STORAGE AND STABILITY
Store the reagent at 2-8^{0}C. DO NOT FREEZE.
The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

PRINCIPLE
Human 'O' Rho (D) positive cells in presence of AGTROL® prediluted reagent do not agglutinate but are sensitized with IgG antibodies. After processing, these sensitized red blood cells are resuspended in red blood cell preserving solution for long term storage and use. When anti-human globulin reagent is added to these sensitized cells the incomplete Anti-D (IgG) antibodies are agglutinated by the anti-human IgG component. The agglutination reaction validates the serological activity of the anti-human globulin reagent and confirms that the anti-human globulin reagent was added in the test procedure.

NOTE
1. In vitro diagnostic reagent for laboratory and professional use only Not for medicinal use.
2. AGTROL® Anti-D (IgG) reagent is not from human source, hence contamination due to HBsAg and HIV is practically excluded.
3. AGTROL® Anti-D (IgG) reagent contains 0.1% sodium azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. Extreme turbidity in both AGTROL® Anti-D (IgG) and red blood cell preserving solution reagent may indicate microbial contamination. Such reagents must be discarded.

SAMPLE COLLECTION AND STORAGE
No special preparation is required prior to sample collection by approved techniques. Samples should be stored at 2-8^{0}C if not tested immediately. Do not use haemolysed samples. Anticoagulated blood using various anticoagulants should be tested within the below mentioned time period: EDTA or Heparin-2 days, Sodium citrate or sodium oxalate-14 days, ACD or CPD-28 days.

ADDITIONAL MATERIAL REQUIRED
Test tubes (12x75 mm), Pasteur pipettes, isotonic saline / isotonic buffered saline, Anti-human globulin reagent (Available from Tulip: ERYCLONE® Anti-human globulin reagent, (Cat.No: 10180002, 10180005), Rho (D) positive red blood cells, Incubator at 37^{0}C, laboratory centrifuge, optical aid.

PROCEDURE
Bring all the reagents to room temperature (25-30^{0}C) before testing.

Preparation and validation of Coombs Control cells

Preparation of 5% Coombs control cell suspension
1. Collect fresh O Rho (D) positive red blood cells preferably with citrate as an anticoagulant.
2. Wash 1ml of freshly collected O Rho(D) positive red blood cells with isotonic saline atleast three times.
3. After the third wash thoroughly decant the supernatant. To the cell button add 5 ml of AGTROL® Anti-D (IgG) reagent and gently resuspend the red blood cells.
4. Incubate the mixture at 37^{0}C for 15 minutes.
5. After incubation wash the sensitized red blood cells thoroughly atleast 4 to 5 times with isotonic saline.

6. Decant the supernatant thoroughly after the last wash. Resuspend the cell button gently with about 1-2 ml of AGTROL® red blood cell preserving solution. The complete resuspended red cells should be added back to the balance AGTROL® red blood cell preserving solution in the dropper vial. A stabilized suspension of 5% Coombs control cells is thus obtained. Label appropriately with the date of preparation.
7. Store the Coombs control cells at 2-8°C. **Use within 4 weeks of preparation.**

Validation of prepared 5% Coombs control cell suspension

1. Add one drop of Coombs control cells into a test tube.
2. Add two drops of Anti-human globulin reagent and mix well.
3. Centrifuge for 1 minute at 1000 rpm or 20 seconds at 3400 rpm.
4. Very gently resuspend the cell button and observe for agglutination macroscopically.

Use of Coombs Control cells

Validation of Antihuman globulin reagent

1. Add one drop of Coombs control cells into a test tube.
2. Add two drops of Anti-human globulin reagent and mix well.
3. Centrifuge for 1 minute at 1000 rpm or 20 seconds at 3400 rpm.
4. Very gently resuspend the cell button and observe for agglutination macroscopically.

Confirmation of negative Antiglobulin test reactions

1. Add one drop of Coombs control cells to the samples negative during Direct or Indirect Antiglobulin test.
2. Centrifuge for 1 minute at 1000 rpm or 20 seconds at 3400 rpm.
3. Very gently resuspend the cell button and observe for agglutination macroscopically.

INTERPRETATION OF RESULTS

Agglutination reaction indicates that the anti-human globulin reagent is functional and the test is valid. No agglutination indicates that the anti-human globulin reagent does not have sufficient activity and the test is invalid.

REMARKS

(1) As undercentrifugation or overcentrifugation could lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and the time required for achieving the desired results. (2) Erroneous results may also occur due to improper red blood cell concentration, improper temperature while performing the test. (3) **Store the Coombs control cells at 2-8°C with cap tightly closed.** (4) **Do not contaminate the prepared Coombs control cell suspension as it may subsequently effect the stability.** (5) **Glassware used to retrieve the AGTROL® reagents and Coombs control cell suspension should be scrupulously clean and sterile.**

WARRANTY

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

BIBLIOGRAPHY

(1) Blood Transfusion in Clinical Medicine, P.L. Mollison, C.P. Engelfriet, Marcela Contreras, 9th Edition 1994, Blackwell Science Publications. (2) AABB Technical Manual, 13th Edition, 1999. (3) Data on File: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

Temperature limitation	Manufacturer	LOT Batch Number/ Lot Number	This side up
Use by	Consult Instructions for use	IVD *In vitro* Diagnostic Medical Device	
Date of Manufacture	REF Catalogue Number	EC REP Authorised Representative in the European Community	

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