Revised February 2007
e631200803_EN

Reagent Red Blood Cells

(Pooled Cells)

Ortho® Coombs Control

A Qualitative Control Test to Confirm the Validity of Negative Antiglobulin Tests

REF

719810
7198041

SUMMARY AND EXPLANATION

ORTHO Coombs Control is used in the laboratory to confirm the validity of negative antiglobulin (Coombs) tests by demonstrating the anti-gamma activity of the anti-human globulin used in the test. It is prepared by sensitizing group O D(Rh_o) positive red blood cells with anti-D(Rh_o) serum capable of agglutinating in albumin. Sufficient anti-D(Rh_o) serum is added to the cells to coat them – but not enough to agglutinate them. When the anti-human globulin in an antiglobulin test does not agglutinate the test cells (a negative reaction), it remains in the test tube in an active state. When the coated red cells in ORTHO Coombs Control are added to the tube, the resultant agglutination indicates both the presence and the activity of the anti-human globulin.

PRINCIPLE OF PROCEDURE

When anti-human globulin is added to a tube containing only washed red cells (as in a compatible crossmatch), the anti-human globulin is unchanged and is capable of agglutinating Coombs control cells. However, if the anti-human globulin has been neutralized by traces of serum globulin – present in the tube because of insufficient washing – it will be unable to agglutinate the sensitized cells and a negative Coombs control test will result.

If the Coombs control test is negative, it indicates that either the anti-human globulin was not added to the crossmatch or that the anti-human globulin was inactive or neutralized. Improper care of the vial of anti-human globulin could also result in a negative Coombs control test. Human serum or plasma accidentally introduced on a pipette or dropper will neutralize the contents of a vial of anti-human globulin. If the control is negative, the antiglobulin test must be repeated since the original result may be invalid.

A positive Coombs control test means the anti-human globulin was added and is detecting antibody globulin adsorbed to the Coombs control cells, indicating adequate washing of the antiglobulin test.

Since anti-human globulin may be unknowingly neutralized through contamination with human serum or plasma, Coombs control cells should be used daily as a quality control procedure to confirm its reactivity.

The agglutination of ORTHO Coombs Control by the anti-human globulin answers the following quality control questions.

1. Confirmation that the anti-human globulin added to the test system is active.
2. Confirmation that anti-human globulin had not been neutralized by residual human protein (either by insufficient washing of the cell/serum mixture or by contamination of the glassware).

REAGENT

ORTHO Coombs Control is a reagent red blood cell product prepared by sensitizing group O red blood cells with IgG antibody. ORTHO Coombs Control is a 3% suspension in a preservative developed by Ortho-Clinical Diagnostics, Inc. – a phosphate-citrate buffered diluent to which a purine, a steroid and nucleosides have been added to maintain reactivity and/or retard hemolysis during the dating period. Chloramphenicol (1:3,000), neomycin sulfate (1:10,000) and gentamicin (1:20,000) have been added to retard bacterial contamination.

ORTHO Coombs Control should be used directly from the vial. It is preferable not to wash or resuspend the cells in saline. As with all reagent red blood cells, the reactivity of the cells may decrease during the dating period. Do not use if marked hemolysis is observed.

For In Vitro Diagnostic Use. Do not freeze. Do not use beyond expiration date. Store at 2 to 8°C.

CAUTION: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

PROCEDURE

Material Provided

ORTHO Coombs Control Reagent Red Blood Cells

Required Supplementary Materials

1. Test tubes, 10 x 75 mm or 12 x 75 mm
2. Centrifuge
3. Anti-human globulin (such as ORTHO Anti-Human Globulin, Anti-IgG, -C3d; polyspecific)

Directions for Use

ORTHO Coombs Control is used in the following manner.

1. Invert the vial several times to resuspend the red cells thoroughly.
2. Add one drop of ORTHO Coombs Control to each presumably negative direct or indirect antiglobulin test or directly to two drops of ORTHO Anti-Human Globulin when confirming the activity of this reagent.
3. Mix well and centrifuge.
   Suggested centrifugation: approximately 15 seconds at 3400 rpm (900-1000 rcf) or 1 minute at 1000 rpm (100-125 rcf).*
4. Resuspend the cells gently and examine *macroscopically only* for agglutination.

Interpretation

1. Agglutination indicates that the anti-human globulin was capable of reacting in the test.
2. No agglutination indicates that the anti-human globulin was inactive, neutralized, or was not added to the test tube.

LIMITATIONS OF PROCEDURE

1. It should be remembered this test will demonstrate only the anti-gamma activity of the anti-human globulin.
2. A positive control does not mean the antiglobulin test was carried out properly; e.g., the patient's serum could have been mistakenly omitted so that a compatible crossmatch resulted but the Coombs control test will still be positive.
3. Contaminated supplementary materials used in the procedure described in this package insert may interfere with the test results.
4. Improper technique may invalidate the results obtained with this reagent.

SPECIFIC PERFORMANCE CHARACTERISTICS

When properly stored and used according to the procedure described under Directions for Use, these cells will confirm that anti-human globulin added to the test system is active and has not been neutralized by residual human protein.

These cells are tested by at least two independent laboratories and are shown to give a standard reaction with ORTHO Anti-Human Globulin.

Technical questions concerning this reagent should be directed to Customer Technical Services at 1-800-421-3311.

*The centrifugal force applied to cell/serum mixtures should be the minimum required to produce a "button" of red cells and a clear supernate.

Overcentrifugation, i.e., the application of forces in excess of the minimum, causes the cells to adhere to the bottom of the test tube so that vigorous agitation is necessary before they can be resuspended. During such agitation, weak agglutination may be dispersed causing a positive reaction to be missed.

Undercentrifugation, i.e., the failure to apply forces necessary to cause the cells to form a "button" and a clear supernate, may result in a weak or negative reaction.

No one speed and time of centrifugation can be recommended which will cover the wide variety of centrifuges available; each laboratory must calibrate its own equipment and determine the time required at a given speed to achieve the desired result.

SUMMARY OF REVISIONS

Removed Italian and German languages.

Removed Distributor addresses.

Added Key to Symbols.

BIBLIOGRAPHY / BIBLIOGRAPHIE / BIBLIOGRAFIA / BIBLIOGRAFÍA

Technical manual. 9th ed. Arlington, VA: American Association of Blood Banks, 1985.
Race RR. Sanger R. Blood Group in man. 6th ed. Oxford: Blackwell Scientific Publications 1975.
Mollison PL. Blood transfusion in clinical medicine, 6th ed. Oxford: Blackwell Scientific Publications 1979.
Arrêté du 8 février 1984 (titre V, article 24), J.O. du 17 mars 1984.
Arrêté du 19 avril 1985, J.O. du 30 mai 1985.
Circulaire du 17 mai 1985 du Ministère des Affaires Sociales et de la Solidarité Nationale.

KEY TO SYMBOLS / LÉGENDE DES SYMBOLES / SYMBOL-LEGENDE / CLAVE DE LOS SÍMBOLOS / LEGENDA DEI SIMBOLI / SIMBOLOGIA / FORKLARING TIL SYMBOLER / ΕΠΕΞΗΓΗΣΗ ΣΥΜΒΟΛΩΝ / FÖRKLARING TILL SYMBOLERNA

The following symbols may have been used in the labeling of this product. / Les symboles suivants ont pu être utilisés pour étiqueter ce produit. / Es ist möglich, dass die folgenden Symbole bei der Etikettierung dieses Produktes verwendet wurden. / Los siguientes símbolos pueden haber sido empleados en el etiquetado de este producto. / Nelle etichette di questo prodotto possono essere stati utilizzati i simboli seguenti. / Os seguintes símbolos podem ter sido utilizados no rótulo deste produto. / Følgende symboler kan være anvendt ved mærkningen af dette produkt. / Τα ακόλουθα σύμβολα ενδέχεται να έχουν χρησιμοποιηθεί στη σήμανση αυτού του. / Följande symboler kanha använts vid märkningen av denna produkt.

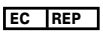
Attention: See instructions for use / Attention : Se référer aux instructions d'utilisation / Wichtig: Siehe Gebrauchsanweisung / Atención: Ver las instrucciones de uso / Attenzione: Vedi le istruzioni per l'uso / Atenção: Consulte as instruções de utilização / Obs.: Se brugsanvisning / Προσοχή: Βλέπετε οδηγίες χρήσης /Obs! Se bruksanvisningen

Lot Number / Numéro de lot / Loscode / Número de lote / Lotto numero / Número de lote / Lot-nummer / Αριθμός παρτίδας / Lot-nummer

Use by/expiration date (CCYY-MM-DD) / Utiliser avant/date d'expiration (AAAA-MM-JJ) / Benutzen vor / Verfallsdatum (JJJJ-MM-TT) / Úsese antes de/Fecha de caducidad (SSAA-MM-DD) / Data di scadenza (AAAA-MM-GG) / Utilizar até/data de validade (SSAA-MM-DD) / Anvendes senest/udløbsdato (ÅÅÅÅ-MM-DD) / Ανάλωση μέχρι/ημερομηνία λήξης (AAEE-MM-HH) / Används före/Utgångsdatum (ÅÅÅÅ-MM-DD)

Store between / Conserver entre / Lagern zwischen / Almacenar entre / Conservare ad una temperatura tra / Armazenar entre / Opbevares mellem / Φύλαξη μεταξύ / Förvaras mellan

For In Vitro Diagnostic Use / Pour Diagnostic In Vitro / In-vitro-Diagnostikum / Para uso diagnóstico in vitro / Per uso diagnostico in vitro / Para diagnósticos In Vitro / Til diagnostisk brug in vitro / Για διαγνωστική χρήση In Vitro / För diagnostisering in vitro



Authorized Representative / Mandataire / Bevollmächtigter / Representante autorizado / Rappresentante autorizzato / Representante Autorizado / Autoriseret repræsentant / Εξουσιοδοτημένος Αντιπρόσωπος */ Auktoriserad representant*

Product Code / Code produit / Artikelnummer / Código del producto / Codice prodotto / Código do Produto / Produktkode / Κωδικός Προϊόντος / Produktkod

This end up / Haut / Diese Seite nach oben / Este extremo hacia arriba / Questa estremità in alto / Este Lado Para Cima / Denne side op / Η Συσκευασία Πρέπει να Είναι Όρθια από Αυτήν την Πλευρά / Denna sida upp

Ortho-Clinical Diagnostics, Inc.
a Johnson & Johnson company
Raritan, New Jersey 08869