CHECKCELL®
CHECKCELL® (Weak)
IgG-Coated Pooled Red Blood Cells

- IVD For in vitro diagnostic use
- Directions Enclosed
- Antiglobulin Control
- Do not use if markedly hemolyzed
- No US standard of potency

°C 10°C Store at 1-10 C. DO NOT FREEZE

servatives: chloramphenicol (0.25 mg/mL), ycin sulfate (0.1 mg/mL), gentamycin sulfate (0.05 mg/mL)

CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. THE PACKAGING OF THIS PRODUCT (DROPPER BULBS) CONTAINS DRY NATURAL RUBBER.

Manufacturer: Immucor, Inc.
Norcross, GA 30071 USA

EC REP Authorized Representative: ImmucorGamma Benelux, 6220 Charleroi BELGIUM

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CHECKCELL®
CHECKCELL® (Weak)
Antiglobulin Control
IgG-Coated Pooled Red Blood Cells

IMMUCOR GAMMA

Intended Use:
Checkcell and Checkcell (Weak) are used to confirm the validity of negative antiglobulin tests.

Summary of the Test:
The antiglobulin test is the primary means by which many red cell antigen-antibody interactions are detected.[1-3] This technique is performed as a routine part of antibody detection, antibody identification and crossmatch tests. Antiglobulin reagents can be rendered nonreactive by unbound serum immunoglobulins. For this reason, it is essential that appropriate controls be included to ensure proper performance of the reagent. Checkcell and Checkcell (Weak), pools of group O red blood cells sensitized (coated) with IgG, is used to confirm the validity of negative antiglobulin tests obtained with Anti-Human Globulin that contains an anti-IgG component, eg, polyspecific Anti-Human Globulin, oligospecific Anti-IgG, monospecific Anti-IgG (heavy chain specific).

Principle of the Test:
Negative antiglobulin results are valid only when active Anti-Human Globulin has been added to tubes containing sufficiently washed and unsensitized red blood cells. ely negative results will occur if the Anti-Human Globulin has been:

1. inactivated by residual serum globulins following improper (incomplete) washing of test red blood cells,
2. inactivated through reagent contamination prior to testing, or
3. omitted from the test system.

Checkcell or Checkcell (Weak) is added to all negative antiglobulin tests. Anti-Human Globulin that does not agglutinate properly washed red blood cells in an antiglobulin test should remain in the active state and should be capable of agglutinating Checkcell or Checkcell (Weak). If Anti-Human Globulin has been omitted from the test system, or it has been inactivated, no agglutination of the Checkcell or Checkcell (Weak) reagent will occur. Tests in those tubes in which Checkcell or Checkcell (Weak) is negative must be repeated and the original results considered invalid.

Reagents:
Checkcell is a single vial pool of group O red blood cells that have been sensitized with an IgG antibody. These red blood cells have been prepared as a 4-6% suspension in a buffered preservative solution containing adenosine and adenine to retard hemolysis during the dating period.

Checkcell (Weak) is a single vial pool of group O red blood cells that have been sensitized with an IgG antibody. These red blood cells have been prepared as a 2-3% suspension in a buffered preservative solution containing adenosine and adenine to retard hemolysis during the dating period. Checkcell (Weak) provides a more sensitive indication of partial neutralization of the anti-IgG component of Anti-Human Globulin.

Chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL) and gentamycin sulfate (0.05 mg/mL) are added as preservatives.

Precautions:
For in vitro diagnostic use.

No US standard of potency.

spend the red blood cells before use by gently inverting the vial several times.

re at 1-10 C when not in use. Do not freeze or expose to elevated temperatures.

Avoid contaminating this product during use. Contamination will adversely effect the product's performance during its shelf life. Do not use contaminated reagents. Do not use beyond the expiration date. Do not use leaking vials. Do not use unlabeled vials.

Antiglobulin control cells should not be used if the cells darken, spontaneously clump, or if there is significant hemolysis. Slight hemolysis may occur with age.

Handle and dispose of reagent as if potentially infectious.

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. THE PACKAGING OF THIS PRODUCT (DROPPER BULBS) CONTAINS DRY NATURAL RUBBER.

The format for the expiration date is expressed as CCYY-MM-DD (year-month-day).

Procedure:
Materials Provided:
Checkcell or Checkcell (Weak), in dropper vials ready for use

Additional Materials Required:
1. Test tube rack
2. Serologic centrifuge

Test Method
1. Perform direct or indirect antiglobulin procedures according to in-house standard operating procedures.
2. Gently invert the vial several times to achieve a complete resuspension of the red blood cells.
3. Add 1 drop of Checkcell or Checkcell (Weak) to each negative antiglobulin test. NOTE: IgG-sensitized red blood cells should be used to confirm the validity of negative reactions obtained in tests employing either uncolored or green colored Anti-Human Globulin. The presence of green dye in a test is only an indication that Anti-Human Globulin has been added. It does not provide assurance that the reagent is reactive.
4. Mix the contents of each tube thoroughly then centrifuge each tube.*
5. Gently suspend each cell button and examine macroscopically for agglutination. Record results.

*Suggested centrifugation time 15-30 seconds at 900-1000 x g or a speed and time appropriate for the centrifuge used.

Stability of Reaction:
Following centrifugation, all tests should be read immediately and results interpreted without delay. Delays may result in dissociation of antigen-antibody complexes leading to falsely negative, or at most, weakly positive reactions.

Quality Control:
The reactivity of Checkcell and Checkcell (Weak) can be determined by testing the reagent in the following manner:

Positive Control – 1 drop of Checkcell or Checkcell (Weak) plus Anti-Human Globulin in the amount specified by the manufacturer's product insert.

Negative Control – 1 drop of Checkcell or Checkcell (Weak) plus 2 drops of saline.

If the cells fail to react in the positive control, or if they react in the negative control, the cells should not be used.

Interpretation of Results:

Positive: agglutination of red blood cells
Negative: no agglutination of red blood cells

Agglutination of 2+ or greater in each previously negative antiglobulin test is an indication that the Anti-Human Globulin was added to each test and was active during testing.

Agglutination of less than 2+ in each previously negative antiglobulin test may indicate that the results obtained may be invalid and the tests should be repeated. Reactions of less than 2+, when consistently obtained, are an indication that the washing method, centrifugation speed or resuspension methods used are not optimal. (See LIMITATIONS.)

NOTE: Weaker agglutination of Checkcell or Checkcell (Weak) than is normally observed may indicate partial neutralization of the antiglobulin reagent. Partial neutralization can lead to a loss of ability to detect weakly reactive antibodies. Tests in those tubes in which there is no agglutination of the cells, or are where the cells are agglutinated much more weakly than expected, should be repeated as the original results may be invalid.

Limitations:

A positive result obtained with Checkcell or Checkcell (Weak) reagent red blood cells does not ensure that the antibody detection or identification test was performed properly or that the test was sufficiently sensitive to detect all unexpected antibodies present in a test serum.

Checkcell and Checkcell (Weak) will only demonstrate the anti-IgG activity of an antiglobulin reagent. This product should not be used to validate negative results obtained with Anti-Human Globulin reagents lacking anti-IgG, eg, monospecific Anti-C3d etc.

Checkcell should produce reactions of 2-4+ and Checkcell (Weak) should produce reactions of 2-3+ in a properly calibrated test system. Failure to achieve the stated results indicates the test system is not performing optimally. Most frequently, weak results are an indication the washing technique is not sufficient to remove all contaminating serum proteins. Increase the volume of saline used or, if employing an automated cell washing device, increase the number of washes. The use of test red blood cell suspensions that are heavier than 5% can also cause an undesirable reduction in the strength of agglutination obtained with this reagent.

Specific Performance Characteristics:

Before release, each lot of Checkcell and Checkcell (Weak) is tested by the insert method and shown to give a standard reaction with Anti-Human Globulin containing anti-IgG. The performance of this product is dependent upon adhering to the insert's recommended methodology. Additional information regarding testing performed at the time of manufacture may be furnished upon request by consulting Immucor's Technical Service at 800-492-BLUD (2583) or 770-441-2051.

The expiration date is set at 60 days from the date of manufacture which is the earliest date that blood is withdrawn from any donor used in a component of the product.

Bibliography:

1. Brecher, ME, ed. Technical manual. 14th ed. Bethesda MD: American Association of Blood Banks, 2002.
2. Issitt PD, Anstee DJ. Applied blood group serology. 4th ed. Durham NC: Montgomery Scientific Publications, 1998.
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- Antiglobulin Control
- Do not use if markedly hemolyzed
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Use:
Checkcell is a single vial pool of group O red blood cells that have been sensitized with an IgG antibody. These red blood cells have been prepared as a 4-6% suspension in a buffered preservative solution containing adenosine and adenine to retard hemolysis during the dating period.

Checkcell (Weak) is a single vial pool of group O red blood cells that have been sensitized with an IgG antibody. These red blood cells have been prepared as a 2-3% suspension in a buffered preservative solution containing adenosine and adenine to retard hemolysis during the dating period. Checkcell (Weak) provides a more sensitive indication of partial neutralization of the anti-IgG component of Anti-Human Globulin.

Chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL) and gentamycin sulfate (0.05 mg/mL) are added as preservatives.

Precautions:
For in vitro diagnostic use.

No US standard of potency.

Resuspend the red blood cells before use by gently inverting the vial several times.

Store at 1-10 C when not in use. Do not freeze or expose to elevated temperatures.

Avoid contaminating this product during use. Contamination will adversely affect the product's performance during its shelf life. Do not use contaminated reagents. Do not use beyond the expiration date. Do not use leaking vials. Do not use unlabeled vials.

Antiglobulin control cells should not be used if the cells darken, spontaneously clump, or if there is significant hemolysis. Slight hemolysis may occur with age.

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Deleted: In this instance the red cells may be washed and suspended in saline immediately prior to use. ¶

Procedure:
Materials Provided:
Checkcell or Checkcell (Weak), in dropper vials ready for use

Additional Materials Required:
1. Test tube rack
2. Serologic centrifuge

Test Method
1. Perform direct or indirect antiglobulin procedures according to in-house standard operating procedures.
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Stability of Reaction:
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Quality Control:
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Positive Control – 1 drop of Checkcell or Checkcell (Weak) plus Anti-Human Globulin in the amount specified by the manufacturer's product insert.

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The reactivity of Reagent Red Cells may diminish over the dating period. The rate at which antigen reactivity (ie, agglutinability) is lost is partially dependent upon the individual donor characteristics that are neither controlled nor predicted by the manufacturer.¶

Specific Performance Characteristics:

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