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

IVD For in vitro diagnostic use

Store at 1-10 C. DO NOT FREEZE

pervadves: chloramphenicol (0,25 mg/mL), ycin sulfale (0,1 mg/mL), gentamycin sulfale (U.05 mg/mL)

Directions Enclosed

Antigiobulin Control

Do not use if markedly hemolyzed

No US stanciard of potency

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

Menujaglurer: Immuoor, Inc. Norgrose, GA 30071 USA

307-12~

SC REP Authorized ImmusorGamma Benakux.

#### Intended Use:

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

The antiglobulin test is the primary means by which many red cell antigen-antibody interactions are detected. 12 This technique is performed as a routine part of antibody Interactions are getected. In this recontique is performed as a routine part of antibody detection, antibody identification and crossmatch tests. Antiglobulin reagents can be repaired populate 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 (coaled) 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 antiglobylin 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:

-inactivated by residual serum globulins following improper (incomplete) washing

of test red blood cells,

inactivated through reagent contamination prior to testing, or 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 calls 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 or mitted from the test system, or it has been inactivated, no agglutination of the Checkcell or Checkcell (Weak) is 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 edenosine and adentine to retard hemolysis during the dating period. Checkcell (Weak) provides a more sensitive Indication of partial neutralization of the anti-log component of Anti-Human Globulin.

Chloremphenicol (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 polency.

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.

# **CHECKCELL®** CHECKCELL® (Weak) **Antiglobulin Control**

NO.989. P.5/6

**IgG-Coated Pooled** Red Blood Cells



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 visits. Do not use unjabeled visits.

Antiglobulin control calls 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 PERIVED 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).

#### Materials Provided:

Checkcell of Checkcell (Weak), in dropper vials ready for use

#### Additional Materials Required:

- Test tube rack
- Serologic centrifuge

#### **Test Method**

- Perform direct or indirect antiglobulin procedures according to in-house standard operating procedures.
- Gently invert the vial several times to achieve a complete resuspension of the red blood cells.
- Add 1 drop of Checkcell or Checkcell (Weak) to each negative antigiobulin 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 due in a test is only an indication that Anti-Human Globulin has been added. It does not provide assurance that the reagent is reactive.
- Mix the contents of each tube thoroughly then centrifuge each tube. 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 disacciation of antigen-antibody complexes leading to faisely 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 Chackcell or Chackcell (Weak) plus Anti-Human Globulin in the amount specified by the manufacturer's product insert.

Negative Control - 1 drop of Chackcell or Chackcell (Weak) plus 2 drops of saline.

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

#### Interpretation of Results:

witive: agglutination of red blood cells ive: no agglutination of red blood cells

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

Aggintination 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, contribugation 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 reagant. 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 entibodies present in a test serum.

Checkcell and Checkcell (Weak), will only demonstrate the anti-IgQ activity of an antiglobulin reagent. This product should not be used to veildate negative results obtained with Anti-Human Globulin reagents tacking anti-IgQ, 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

its are an indication the washing technique is not sufficient to remove all aminating serum proteins. Increase the volume of saline used or, if employing an complete 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 (umished 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:

- Brecher, ME, ed. Technical manual. 14th ed. Bethesda MD: American Association of Blood Banks, 2002.
- Issltt PD, Anstee DJ. Applied blood group serology, 4th ed. Durham NC: Montgomery Scientific Publications, 1998.
- Mollison PL. Engelfriet CP, Contreras M. Blood transfusion in clinical medicine.
   9º ed. Oxford: Blackwell Scientific, 1993.

CE

Insert code 307-12 Rev 9/04

CHECKCELL® CHECKCELL® (Weak)

IgG-Coated Pooled Red Blood Cal

• IVD For In vitro diagnostic use

• Directions Enclosed

100 1000 Store on 1-10 C. DO NOT FREEZE Preservatives: chloramothenicol (0,25 mg/ml.), woln sulfate (0,1 mg/ml.), gentemych autore

Antiglobulin Control

 Do not use if markedly hemolyzed. No US granderd of potency

ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS, RACING OF THIS PRODUCT (DROPPER BLLBS) CONTAINS DRY NATURAL

## **CHECKCELL®** CHECKCELL® (Weak) **Antiglobulin Control**

laG-Coated Pooled **Red Blood Cells** 

Pormatted: Font: Times New Roman, Border: : (No border)

Formatted: Bullets and Numbering

Delicitari: In this instance the rad cells may

be weated and suspended in saline immediately prior to use. ¶

ebjer keriyan; his Montan, GA 10071 USA

307-12~

**IMMUCOR** 

Deleted; 1

Deleted: Belglum S.A.

Deleted: Regent and

Intended Use: ampantaru valas. Checkeell prod (Cinckeell (N)eakl) pro used to conform the validity of negative ambalopulities.

Summer of the Test:

Summary of the Teet:
The antiglouin test is the primary queens by which many red cell entigen-entillady interestions are detected.<sup>14</sup> This technique is performed as a routher part of entibody interestions are detection, antibody identification and creamplish tests. Antiglobulin respects can be rendered connective by unbound serum immunoglobulins. For this mason, it is essential that appropriate control to be included to entere proper performance of its essential that appropriate control to the proper performance of the content with pict, is used to continue the validity of registive antiglobulin tests obtained with Anti-Human Globulin that content on entirely content in the sufficient performance of the pict.

Human Globulin, dispersectific Anti-log, management of Anti-log (heavy chain specific).

Principle of the Test:

Principle of the least Negative antiglobulin results are valid only when active Arti-Human Globulin has been added to takes containing sufficiently weathed and unawnatized red blood cells. Falsely negative results will occur if the Arti-Human Globulin has been:

1. Inactivated by residual serum globuline following improper (incomplete) washing

of tast red blood calls.

inactivated through reagent contamination prior to testing, or omitted from the test system.

Checkcoll of Checkcoll (Weel) is added to all negative ambilobulin texts. Anti-Human Globulin that does not applicinate properly weaked red blood cells in an ambilobulin test should remain in the active state and should be capable of applicinating Checkcoll (Meek). If Anti-Human Globulin has been omitted from the text system, or it has been inediteded, no applicination of the Checkcell or Checkcell (Weel) (Weel) regent will posts. Tasks in those tubes in which Checkcell or Checkcell (Weel) (Weel) (Weel) and market of the checkcell or Checkcell (Weel).

List.

All is a eingle visit pool of group O rad <u>blood</u> cells that have been sometized

while all got entitionly. These rad <u>blood</u> cells have been prepared as a 4-6%
autoporteion in a buffered preservative solution pontaining adequates and adentitio to
related hemotypes during the deting period.

Checkodii (Vising) is a single visi pool of group of red Mand, cells first have been constituted with an IgG antibody. These red Mand cells have been prepared as a 2-3% suspension in a buffered precervative action containing adequate and adentite to report hemotypic during the dating period. Checkes Orbest provides a more sensities, but cells no sensities of sensities and adentite to the sensities of sensities and adentite to the sensities of sensities of sensities.

Chloramphenicol (0,25 mg/mL), neomych sulfate (0.1 mg/mL) and genjamych aufala (0.01 mg/mL) are added as preserval/sea.

For in vitto diennostic use.

No US standard of octanov.

Buspend the red blood calls before use by gently inventing the viel 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. Commination will adversely affect the product's performance during its shell life. Do not use contaminated respents. Do not use beyond the expiration date. Do not use leaking viels. Do not use unlabeled viels.

Anticlobulin control colls should not be used if the cells dayken, exceptaneously clump, \_ or if there is significant hemolysis. Slight hemolysis may occur with age.

Handle and dispose of reagent as If polenitally 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 THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS. THE PACKAGING OF THIS PRODUCT (DROPPER BULBS) CONTAINS DRY NATURAL RUBBER.

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

Procedure:

Checkcell of Checkonii (Week), in dropper viels ready for use

Additional Materials Required:

Test tube rack

Serologic centrituge

Perform direct or indirect antiplobulin procedures according to in-house standard operating procedures.

Gently Invertithe visi several times to achieve a complete resuspension

of the red blood calls.

Add 1 drop of Checkcell or Checkcell (Weak) to each negative anligiobulin test. NOTE: 19G-sepsifized red thood cells should be used to confirm the validity of negative reactions obtained in leste employing although the confirm of the confirmation to continue value of each tube thoroughly then centrifue each tube."

The presence of green does not provide assurance that the reagent is reactive. Mix the contents of each tube thoroughly then centrifue each tube."

Gently suspend each cell button and examine macroscopically for

agglutination. Record results.

"Suggested contributeion time 15-30 seconds at 900-1000 x g or a speed and time appropriate for the contribute used.

Stability of Reaction:

Following centrifugation, all tests should be need immediately and results interpreted without delay. Delays may result in dissociation of antipen-antibody complexes leading to falsely negative, or at most, weakly positive maxilians.

Clusing Composition of Chockosii mid Chinkosii (Week) can be determined by testing the reagent in the following meaner.

Positive Composition of Chinekosii of Chinekosii (Mean) plus Anti-Human.

Globulin in the amount apecified by the manufacturer's product mann.

Deleted: ¶

Deleted: colic

SEP.,28.2004 10:31AM IMMUCOR	NO.939 P.4/6
Negative Control - 1 drop of Checkoell or Checkoell (Week) plus 2 draps of agine.	Deleted: oslja
If the collision to reach in the positive control, or if they react in the negative control, the collision that is used.	
interpretation of Results: Positive: applulination of red <u>blood</u> cells Negative: no applulination of red <u>blood</u> cells	
allon of 2- or greater in each previously negative expligibility test is an statute Ant-Human Globulin was added to each test and was active during	
Appulpation of less than 2+ in each previously negative aphigiobulin rest may indicate that the restitut obtained may be invated and the less should be repeated. Reactions of less than 2+, when consistently obtained, are an indication that the watching method, compliquation appeal or resuspension methods used are not optimal. (See LIMITATIONS.)	
piCTE: Weater aggluination of Checkoff of Checkoff (Weak) then is normally observed may indicate partial neutralization of the antigiobalin reagent. Partial neutralization can lead to a loss of ability in detect weakly reactive antibodies. Tests in those tubes in which there is no aggluination of the calle, of set where the calls are applicated much more weakly than expected, about he repeated as the original results may be liveled.	
Limitations:  A positive result obtained with Checkcell or Chipriscell (Week) reagent red blood calls does not ensure that the antibody detection of identification took was performed properly of that the best was sufficiently sensitive to detect all unexpected antibodies present in a feet securit.	
Checkcell mpd Checkpell (Vések) will only demonstrate the anti-tigg activity of an antiglobush reagets. This product about 1 not be used to velicist negative results obtained with Anti-Human Globulin reagents lacking anti-tigg, eg, monospecific Anti- C3d etc.	
Chephonii should produce relations of 2-4- and Chephonii (Weak) singuid produce readjune of 3-5- in a properly calibrated test system. Failure to exhibite the stated results indicates the lest system is not performing optimally. Most frequently, weak results are an indication the weaking recipitors is not sufficient to remove all concerningting senting proteins. Increase the volume of saline used on it employing an automated oil weaking device, increase the number of washes. The use of past red blood call euterprofeins that are heavier than 3% can also cause an undestrable reduction in the strength of augulation obtained with this reagent.	The reactivity of Reagent Red Cells may diminish over the dating period, The rate at which arriver reactivity (le, suggisting elitity) is lost to partially dependent upon the individual dong characteristics that are relative controlled not predicted by the manufacturer.
Specific Performance Cheracteristics: Before release, each lot of Checkcell and Checkcell (Week) is tested by the keent marked and shown to give a standard reaction with Anti-Human Globulin containing enti-log. The performance of this product is dependent upon adverting to the insent's recommended methodogy. Additional information retenting testing performed at the tipe of marked methodogy and the formation returning testing performed at the content of	
instian date is set at 60 days from the date of menufecture which is the earliest at blood is withdrawn from any donor used in a component of the product.	
Bibliography: 1. Brecher, ME, ed. Technical manual, 44m ed. Bethesda MD: American Association of Blood Banks, 2002.	
Assertation to please payer, 2014.     Health PD, Ansale DJ. Applied blood group serulogy. 4th ed. Durham NC:     Montgomery Scientific Publications, 1998,     Molison PJ, Engelfier CP, Comercias M. Blood transfusion in clinical medicine.     See C. Oxfort Blockwell Scientific, 1993.	
F C Insert code 307.12	