The product is supplied filtered to 0.22 μm.

Techniques without further dilution or additions.

C4d fragments.

Are appropriate. The reagent will not agglutinate red cells coated with diagnostic applications where direct or indirect antiglobulin techniques sub-classes) and C3 fragments bound to red cells in all the routine has been standardised to give optimal detection of human IgG (all four IgG and murine monoclonal Anti-C3d (cell line BRIC-8). The reagent dilutions of sera obtained from rabbits immunised with purified human cells. BIOSCOT Anti-Human Globulin (polyspecific) is a blend of selected C3d) will generally result in clearly visible agglutination of the red blood

The addition of Anti-Human Globulin to thoroughly washed red cells which are coated with antibody (immunoglobulin) and/or fragments of the third component of the complement system (C3b, C3bi, C3dg or C3d) will generally result in clearly visible agglutination of the red blood cells. BIOSCOT Anti-Human Globulin (polyspecific) is a blend of selected dilutions of sera obtained from rabbits immunised with purified human IgG and murine monoclonal Anti-C3d (cell line BRIC-8). The reagent has been standardised to give optimal detection of human IgG (all four sub-classes) and C3 fragments bound to red cells in all the routine diagnostic applications where direct or indirect antiglobulin techniques are appropriate. The reagent will not agglutinate red cells coated with C4d fragments.

The reagent has been optimised for use as supplied by the recommended techniques without further dilution or additions.

The product is supplied filtered to 0.22 μm.
MATERIALS REQUIRED BUT NOT PROVIDED

Indirect Antiglobulin Technique - Normal Ionic Strength Saline (NISS):
- Test tube
- Phosphate buffered saline
- Incubator 37°C
- Timer
- Centrifuge (1000 rcf)
- IgG sensitised red cells (Coombs control cells)

Indirect Antiglobulin Technique - Low Ionic Strength saline (LISS):
- Test tube
- Phosphate buffered saline
- Low Isotonic Strength saline
- Incubator 37°C
- Timer
- Centrifuge (1000 rcf)
- IgG sensitised cells (Coombs control cells)

DIRECT ANTIGLOBULIN TECHNIQUE

2.3 Mix thoroughly and incubate at 37°C for 15 minutes. Continue through stages 1.4 – 1.7 as specified in the indirect antiglobulin technique.

2.1 To a clearly labelled clean glass test tube add 2 drops (80 μl) of the test serum. Add one drop (40 μl) of a 3-5% suspension of test red cells which have been washed three times and resuspended in PBS.

2.2 Add 2 drops (80 μl) of BIOSCOT Anti-Human Globulin (polyspecific) to the dry cell button. Mix thoroughly and centrifuge at 1000 rcf for 20 seconds.

2.4 Wash the cells four times in PBS taking care to decant the washing fluid completely and resuspending the cell button after each wash. Decant the PBS completely after the last wash.

2.5 Resuspend the cells by gentle agitation and read macroscopically. N.B.: vigorous agitation may disrupt weak agglutination.

2.6 The validity of all negative antiglobulin tests should be confirmed by the addition of IgG sensitised red cells (Coombs control cells).

2.7 The use of LISS test cell suspensions enables the incubation time to be reduced to 15 minutes. The sensitivity of the LISS antiglobulin technique is dependent on the use of an equal ratio of serum to red cell suspension. It is therefore, recommended that semi-automated pipettes are used for the addition of serum and cell suspension.

The blood sample tested should be freshly drawn (less than 24 hours) and preferably collected into EDTA anticoagulant.

3.2 To a clearly labelled clean glass test tube add 1 drop (40 μl) of the cell suspension. Continue through stages 1.4 - 1.7 as specified in the indirect antiglobulin technique (NISS).

PERFORMANCE CHARACTERISTICS

Anti-Human Globulin (cell line BRIC-8) polyspecific human IgG/C3d reagent product code TS has been tested by each of the recommended techniques with donor, clinical and neonatal specimens. The total number of tests (n) and the sensitivity and specificity was calculated for each technique and is displayed below:

<table>
<thead>
<tr>
<th>Technique</th>
<th>Anti-Human Globulin Product Code TS</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>IAT (NISS)</td>
<td>0</td>
<td>0</td>
<td>51</td>
</tr>
<tr>
<td>DAT (LISS)</td>
<td>0</td>
<td>0</td>
<td>157</td>
</tr>
<tr>
<td>IAT (LISS)</td>
<td>19</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>DAT (LISS)</td>
<td>13</td>
<td>100</td>
<td>47</td>
</tr>
</tbody>
</table>

Abbreviations: IAT = Indirect Antiglobulin Test. DAT = Direct Antiglobulin Test. NISS = Normal Ionic Strength Saline. LISS = Low Ionic Strength Saline.

REFERENCES


LIMITATIONS

Contamination with human serum and / or inadequate washing will neutralise Anti-Human Globulin.

Clotted blood samples should not be refrigerated prior to direct antiglobulin testing.

False positive or false negative results may occur through contamination of test materials or any deviation from the recommended techniques.