The indirect antiglobulin test will detect, after incubation of serum or plasma with red blood cells, IgG antibodies and/or complement component C3 bound to red blood cells in vitro in applications including antigen typing, antibody detection, and antibody identification.

**PRINCIPLE OF THE TEST**

The Anti-Human Globulin Anti-IgG,-C3d; Polyspecific will cause the agglutination of human red blood cells sensitized with IgG and/or coated with C3d/C3b complement components. No agglutination will be observed with uncoated red blood cells.

**REAGENT DESCRIPTION**

The main components of this reagent are rabbit antibody to human IgG and a monovalent human IgG antibody to C3d (clone number 3G8).

The formulation also contains bovine serum albumin, 0.1% (w/v) sodium azide and between 80. The pH of the reagent is dyed green by the addition of patent blue and tartrazine.

NOT: The volume delivered by the reagent bottle dropper is approximately 40 µL. Care should be taken to ensure that appropriate serum to cell ratios are maintained in all test systems.

**STORAGE**

The reagent should be stored at 2–8 °C.

**WARRIORS AND PRECAUTIONS**

For in vitro diagnostic use only. Products should be used by qualified personnel. Do not use beyond expiration date. Do not freeze. Do not dilute.

The format of the expiration date is expressed as YYYY-MM-DD (Year-Month-Day).

This reagent contains 0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive compounds. If discarded into a sink, flush with a large volume of water to prevent azide buildup.

The reagent is of animal origin, therefore care must be taken during use and disposal as there is a potential infection risk. This product has components (dropper bulbs) containing dry natural rubber.

Contains material of murine origin; therefore, handle appropriately as the absence of murine viruses has not been determined.

**SPECIMEN COLLECTION AND PREPARATION**

Specimens should be collected by a standard collection technique. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at refrigerated temperatures. Do not use blood specimens that exhibit contamination. Extreme care should be taken if hemolysed samples must be tested. Clotted samples, or those collected in EDTA, should be tested within fourteen days from collection. Donor blood may be tested until the expiration date of the donation.

For the Direct Antiglobulin Test it is recommended that testing is performed within 48 hours for blood drawn into EDTA. Blood collected into other anticoagulants may be tested (ACD, CPD, CPDA-1, CP2D, CP2D-AS). Clotted specimens should be tested prior to refrigeration to avoid in vitro sensitization with complement.

Indirect Antiglobulin tests should ideally be performed within 72 hours of collection. If a plasma sample is used, complement dependent antibodies may not be detected.

**MATERIALS**

- **Material provided**
  - Anti-Human Globulin Anti-IgG,-C3d; Polyspecific
  - Clotted serum
  - Human red blood cells
  - Donor or patient red blood cells/serum

**CAUTION: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER**

**INTRODUCTION**

Anti-Human Globulin Anti-IgG,-C3d; Polyspecific is intended for use in the direct antiglobulin test to detect the in vivo coating of human red blood cells with IgG and/or C3d and/or C3d components.

Anti-Human Globulin Anti-IgG,-C3d; Polyspecific is intended for use in the indirect antiglobulin test to detect the in vitro coating of human red blood cells with IgG and/or C3d and/or C3d components.

**SUMMARY AND EXPLANATION**

The antiglobulin test was first used in blood group serology by Coombs, Mount and Race in 1945. The serum of animals immunized with human protein was used to detect 'incomplete' antibodies bound to red blood cells. The ability of antiglobulin reagents to detect human complement components bound to red blood cells was reported by Oseite, Crookston and Christensen in 1957.

The direct antiglobulin test will detect IgG antibodies and/or complement component C3 bound to red blood cells in vivo in serological conditions such as the presence of autoantibodies, antibodies as a result of a transfusion reaction and hemolytic disease of the fetus and newborn.
### SPECIFIC PERFORMANCE CHARACTERISTICS

#### Comparator Study Results

During comparator studies (data on file at Alba Bioscience Limited), blood samples were tested with Anti-Human Globulin Anti-IgG, C3d; Polyspecific as follows:

- **Indirect Antiglobulin Test**

<table>
<thead>
<tr>
<th>Trial Reagent</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>2577</td>
<td>834</td>
<td>3411</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>2588</td>
<td>835</td>
<td>3423</td>
</tr>
</tbody>
</table>

- **A BO Cross-Match**

<table>
<thead>
<tr>
<th>Trial Reagent</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>2577</td>
<td>834</td>
<td>3411</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>2588</td>
<td>835</td>
<td>3423</td>
</tr>
</tbody>
</table>

#### Antibody Identification Process

- **Anti-IgG, Anti-C3d**

<table>
<thead>
<tr>
<th>Trial Reagent</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>2577</td>
<td>834</td>
<td>3411</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>2588</td>
<td>835</td>
<td>3423</td>
</tr>
</tbody>
</table>

#### Direct Antiglobulin Test

- **Anti-IgG, Anti-C3d**

<table>
<thead>
<tr>
<th>Trial Reagent</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>2577</td>
<td>834</td>
<td>3411</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>2588</td>
<td>835</td>
<td>3423</td>
</tr>
</tbody>
</table>

### BIBLIOGRAPHY


### DATE OF ISSUE

2020-01-15

US Distributor
Quotient
301 South State Street
S-204
Newtown
PA 19840
USA
Customer Service Tel: 1-888-294-1901
Product Technical Support Tel: 1-888-228-1990
Customer Service Fax: 1-888-694-5208
E-Mail: customer.serviceUS@quotientbd.com
Web: www.quotientbd.com

Alba Bioscience Limited
James Hamilton Way
Pericuil
EH26 0SF
UK
Tel: +44 (0) 131 357 3333
Fax: +44 (0) 131 445 7125
E-Mail: customer.serviceEU@quotientbd.com

Alba Bioscience Limited 2020
Z350U/Z351UP/01

© Alba Bioscience Limited 2020

**Precision Study Results**

As part of the performance evaluation, precision and lot to lot studies were performed using multiple operators, days and runs to confirm repeatability and reproducibility of test results in the same run, day and with the same operator and between runs, days and operators. The study took account of variables such as days of the week, times of day and supplementary reagents used in testing.

There were no discordant results; all expected positive test outcomes generated unequivocal positive reactions and all expected negative test outcomes generated unequivocal negative reactions.

Prior to release, each lot of Anti-Human Globulin Anti-IgG, C3d; Polyspecific is tested using FDA recommended methods against IgG sensitized and complement coated red blood cells to ensure reactive sensitivity.