INTENDED USE
This Anti-c reagent is for the in vitro detection and identification of the human c blood group antigen by direct agglutination.

PRINCIPLE OF THE TEST
When used as recommended, this reagent will cause agglutination (clumping) of red blood cells carrying the c antigen. Lack of agglutination demonstrates the absence of the c antigen.

REAGENT DESCRIPTION
The main component of this reagent is derived from the in vitro culture of the IgM secreting human/mouse heterohybridoma H48. The formulation contains 20 g/l BSA and 0.1% (w/v) sodium azide in PBS. The volume delivered by the reagent dropper bottle is approximately 40 µL; bearing this in mind, care should be taken to ensure that appropriate serum: cell ratios are maintained in all test systems.

STORAGE CONDITIONS
The reagent should be stored at 2-8 °C. Do not use if turbid. Do not dilute. The reagent is stable until the expiry date stated on the product label.

PRECAUTIONS FOR USE AND DISPOSAL
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 sink, flush with a large volume of water to prevent azide buildup. CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT IS DERIVED WAS FOUND NON-REACTIVE FOR HIV, HBV, HCV. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS DISEASE. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT. This product has components (dropper bulbs) containing dry natural rubber. This reagent is for in vitro diagnostic use only.

SPECIMEN COLLECTION AND PREPARATION
Specimens should be collected by a standard collection technique. The specimen should be stored at refrigerated temperatures. Blood specimens exhibiting contamination should not be used. Extreme care should be taken if hemolyzed 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 expiry date of the donation.

TEST PROCEDURES
General Information
This reagent has been standardized for use by the technique described below and therefore its suitability in other techniques cannot be guaranteed. When a test is required to be incubated for a specific time period, a timer should be used.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED
- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-c
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Centrifuge
- Heating block / waterbath
- Timer

RECOMMENDED TECHNIQUES
Tube Technique - 5-15 Minute Incubation / Spin
- Add 1 drop of blood grouping reagent to a test tube.
- Add 1 drop of red blood cells suspended to 2.4% in isotonic saline. Reagent red cells may be tested as provided (preservative suspended).
- Mix the contents of the test tube well and incubate at 37 °C ± 1 °C for 5-15 minutes.
- Centrifuge the test tube.
- Suggested centrifugation: 1000 g (approx. 3400 rpm) for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive red blood cells, yet allows easy re-suspension of antigen-negative red blood cells.
- After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

INTERPRETATION OF RESULTS
Agglutination = positive test result
No agglutination = negative test result

QUALITY CONTROL
Quality control of reagents is essential and should be performed on each day of use and in accordance with local, state and federal regulations. We suggest that the following red blood cell samples are used to control the reactions of this reagent.

- c+c+ red blood cells should be used as a positive control.
- c-c+ red blood cells should be used as a negative control.

False positive test results are rarely seen with low-protein reagents. False positive agglutination may be due to a positive direct antiglobulin test (DAT), cold agglutinins, or abnormal serum proteins. If false positive results are suspected, or local regulations require, and a control test for spontaneous agglutination is desired, ALBAcheck® - BGS Monoclonal Control (Z271U) or 6-10% albumin in saline may be substituted for the blood grouping reagent in the testing procedure. A negative result would serve as an appropriate control. If the monoclonal control test gives a positive reaction, a valid interpretation of the results obtained in red blood cell testing cannot be made without further investigation.

PERFORMANCE LIMITATIONS
Driblocks and waterbaths promote better heat transfer and are recommended for 37 °C tests, particularly where the incubation period is 30 minutes or less.

The expression of certain red blood cell antigens may diminish in storage during transportation, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.

Gently re-suspend tube tests before reading. Excessive agitation may disrupt agglutination and produce false negative results.

Excessive centrifugation can lead to difficulty in resuspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, omission of test reagents and certain disease states.

The main component of this reagent is derived from the in vitro culture of the IgM secreting human/mouse heterohybridoma, H48. It should be noted that cell line H48 may show reduced or no reactivity with the c variant Rh-26. It is possible that this antibody may show reduced or no reactivity with other rare variants of the c antigen.

Care should be taken when testing red blood cells that have been treated with proteolytic enzymes, as these may produce false positive or false negative results.

SPECIFIC PERFORMANCE CHARACTERISTICS
Prior to release, each lot of ALBAclone® Anti-c is tested by FDA recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

Comparator Study Results
During comparator studies (data on file at Alba Bioscience Limited), blood samples were tested with ALBAclone® Anti-c (Monoclonal) as follows:

<table>
<thead>
<tr>
<th>Comparator Reagent</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-c</td>
<td>177</td>
<td>0</td>
<td>177</td>
</tr>
<tr>
<td>Trial Reagent</td>
<td>177</td>
<td>0</td>
<td>200</td>
</tr>
<tr>
<td>Positive Percent Agreement*</td>
<td>100</td>
<td>96.32</td>
<td></td>
</tr>
<tr>
<td>Negative Percent Agreement*</td>
<td>100</td>
<td>87.79</td>
<td></td>
</tr>
</tbody>
</table>

* The data presented in this table was generated during field trials executed in support of the original US licensing of this reagent.
BIBLIOGRAPHY


DATE OF ISSUE
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