ALBAcheck® - BGS Monoclonal Control

INTENDED PURPOSE
ALBAcheck® - BGS Monoclonal Control is intended for use as a negative control in conjunction with Alba Bioscience Limited monoclonal blood grouping reagents (where referenced in the reagent IFU).

REAGENT DESCRIPTION
This reagent is formulated in a similar manner as Alba Bioscience Limited monoclonal blood grouping reagents. The reagent also contains EDTA and 0.1% (w/v) sodium azide. 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. As this reagent contains material of animal origin 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. This reagent is for in vitro diagnostic use only.

TEST PROCEDURES
General Information
ALBAcheck® - BGS Monoclonal Control should be substituted for, and used by, the recommended techniques for the monoclonal blood grouping reagent being controlled.

The reagent should be warmed to room temperature prior to use.

INTERPRETATION OF RESULTS
If a positive result is obtained with ALBAcheck® - BGS Monoclonal Control, this will invalidate the test result obtained when testing red blood cells with the respective Alba Bioscience Limited monoclonal blood grouping reagent.

PERFORMANCE LIMITATIONS
Unexpected reactivity can occur due to contamination of test materials, improper reaction temperature, improper storage of materials and omission of test reagents.

SPECIFIC PERFORMANCE CHARACTERISTICS
Prior to release, each lot of ALBAcheck® - BGS Monoclonal Control is tested by procedures to verify its intended use as a control for low protein blood grouping reagents.

COMPARTER STUDY RESULTS
During comparator studies performed at Alba Bioscience Limited, blood samples were tested with ALBAcheck® - BGS Monoclonal Control as follows:

<table>
<thead>
<tr>
<th>Monoclonal Control</th>
<th>Trial/Comparator Reagent</th>
<th>Comparator Reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Trial Reagent</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>100</td>
</tr>
</tbody>
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BIBLIOGRAPHY

DATE OF ISSUE
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