BOVINE SERUM ALBUMIN 22%



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

INTERPRETATION OF LABELING SYMBOLS



Batch code

Use by (YYYY-MM-DD)



IVD

Storage temperature limitation (2-8 °C)

In vitro diagnostic medical device



Consult instructions for use



Product code



Manufacturer

INTENDED USE

This Bovine Serum Albumin reagent is intended for the potentiation of agglutination reactions in blood group serology tests.

SUMMARY AND EXPLANATION

Bovine serum albumin (BSA) has various applications in blood group serology. This product (provided as a 220g/L solution) can be used to potentiate the reactions of blood group antibodies that do not directly agglutinate red cells (generally added at 200g/L for this purpose), to potentiate hemagglutination reactions in automated blood grouping equipment or microplate test methods and to stabilize blood grouping reagents.

REAGENT DESCRIPTION

The formulation also contains 0.1% (w/v) sodium azide. NOTE: The volume delivered by the reagent bottle dropper is approximately 40 μ L. 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.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only Products should be used by qualified personnel Do not use beyond the expiration date Do not use if turbid 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. This reagent is of animal origin, therefore care must be taken during use and disposal as there is a potential infection risk.

The bovine material which used in the manufacture of this reagent was collected in a USDA approved facility. This product has components (dropper bulbs) containing dry natural rubber.

MATERIALS

Material provided

Bovine Serum Albumin

PROCEDURE

Bovine Serum Albumin has various applications in blood group serology. Users are advised to carefully confirm reagent suitability before use in specific procedures.

For example:

Bovine Serum Albumin 22% may be used as an enhancement media for antibody detection or identification in a 1:1 ratio with serum or plasma being tested. Standard recommended incubation times are 30-60 minutes at 37 °C \pm 1 °C, prior to the indirect antihuman globulin phase of testina. $^{12.3}$

QUALITY CONTROL

The efficacy of albumin reagents should be controlled throughout their use.

PERFORMANCE LIMITATIONS

Agglutinins to albumin are found in a small proportion of serum samples.

As provided, this reagent should not be used as a negative control for low protein potentiated IgG blood grouping reagents. The product may be diluted to 6-10% suspension for use as a control with low protein blood grouping reagents.

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.

BIBLIOGRAPHY

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- Judd's Methods in Immunohematology, Third Edition. W. John Judd, et al. Bethesda, MD: AABB Press, 2008.
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