

BOVINE SERUM ALBUMIN 22%

This insert refers to product Z305U

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

INTERPRETATION OF LABEL SYMBOLS

LOT

Batch code



Use by (YYYY-MM-DD)



Storage temperature limitation (2°C– 8°C)

IVD

In vitro diagnostic medical device



Consult instructions for use

X_n

Harmful



Manufacturer

INTRODUCTION

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 haemagglutination reactions in automated blood grouping equipment or microplate test methods and to stabilise blood grouping reagents.

INTENDED PURPOSE

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

REAGENT DESCRIPTION

This reagent has been prepared from a closed herd in the female line since 1980, in which no animal has been clinically suspected of having bovine spongiform encephalopathy (BSE), and has not been fed rations containing ruminant-derived protein during that period.

The volume delivered by the reagent dropper bottle is approximately 40µl. Bearing this in mind, care should be taken to ensure that appropriate serum:cell ratios are maintained in all test systems.

This reagent complies with the requirements of Directive 98/79/EC on *in vitro* Diagnostic Medical Devices and the recommendations contained in the Guidelines for Blood Transfusion Services in the United Kingdom.

STORAGE CONDITIONS

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

PRECAUTIONS FOR USE AND DISPOSAL

This reagent contains 0.1% sodium azide (EC No.247-852-1) and is classified as harmful (X_n). R22 Harmful if swallowed. Sodium azide 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 is of animal origin care must be taken during use and disposal as there is a potential infection risk. This reagent is for *in vitro* professional use only.

TEST PROCEDURES

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

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.

This reagent should not be used as a negative control for potentiated IgG 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.

DATE OF ISSUE

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