BIOSCOT®

Anti-S

Monoclonal Human IgM

Blood Grouping Reagent

Cell Line: MS-94

CE 0123 IVD

REF TJ-2ML-B
TJ-10X2ML-B

Tube Technique

INTENDED USE

BIOSCOT® Anti-S (cell line MS-94) monoclonal human IgM blood grouping reagent is used to ensure the immunological compatibility of blood and blood components intended for transfusion. This qualitative reagent will detect the presence or absence of the S (MNS3) antigen on the surface of human red blood cells when tested according to the tube technique. The reagent is designed for in vitro diagnostic, professional use by operators trained in serological techniques.

PRINCIPLE OF THE REAGENT

When used by the recommended technique this reagent will cause agglutination (clumping) of red cells carrying the specific antigen (positive test). Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).

The reagent has been characterised by the procedure recommended in these instructions for use, its suitability for use in other techniques must be determined by the user.

PRECAUTIONS

1. All blood products should be treated as potentially infectious. The human donor or the cell line used to produce this reagent has been tested and found to be negative for Anti-HIV, Anti-HCV, HBsAg, EBV and Mouse Antibody Production (MAP) viruses. No known tests can guarantee that any product derived from human blood is free from infectious agents. Care must be taken in the use and disposal of each container and its contents.
2. The reagent contains 0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead or copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
3. This product should be clear. Turbidity may indicate bacterial contamination. The reagent should not be used if a precipitate, fibrin gel or particles are present.
4. The bovine material is obtained from USDA approved sources or from sources for which origin information is available. The donor animals have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.
5. The product should be disposed of either by overnight immersion in disinfectants at appropriate concentrations or by autoclaving.

CONTROLS

It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions.

It is not required to use a reagent control in parallel with all tests using this reagent. Only in typing the red cells of patients known to have auto-antibodies or protein abnormalities is the use of a reagent control such as BIOSCOT® Monoclonal Control (Product code: TT) recommended. This should be tested in parallel with the reagent.

STORAGE

Store the opened / unopened product at 2-8°C until the expiry date detailed on the product label.

Failure to store the products at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing, may result in accelerated loss of reagent activity.

SPECIMEN COLLECTION

No special preparation of the patient/donor is required prior to specimen collection. Blood should be collected by an approved phlebotomy technique into tubes containing EDTA or CPD. The specimen should be tested as soon as possible following collection. Samples that cannot be tested within 24 hours of collection should be stored at 2-8°C. Testing should be carried out within 14 days of collection. Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent. Failure to store the specimens in the correct conditions may result in false positive or false negative results.

MATERIALS PROVIDED

Product code TJ Anti-S blood grouping reagent contains antibody from cell line MS-94. The reagent is composed of monoclonal human IgM antibodies in a buffer solution containing macromolecular chemical potentiators. The reagent contains 0.1% (w/v) sodium azide and bovine material. The product is supplied filtered to 0.22 µm. The reagent has been optimised for use by the recommended techniques without further dilution or additions.

Contents:
1 x reagent vial for REF TJ-2ML-B.
10 x reagent vials for REF TJ-10X2ML-B.
1 x information sheet

MATERIALS REQUIRED BUT NOT PROVIDED

Tube Technique:

- Test tube
- Isotonic saline
- Timer
- Centrifuge (1000 rcf)

RECOMMENDED TECHNIQUE

1. TUBE TECHNIQUE

1.1 Prepare a 3-5% suspension of test red cells in isotonic saline.
1.2 Add 1 drop (40-50 µl) of Anti-S reagent to an appropriately labelled test tube.
1.3 Add 1 drop (40-50 µl) of the suspension of test red cells.
1.4 Mix and centrifuge at 1000 rcf for 20 seconds.
1.5 Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.
1.6 Incubate all negative or weakly positive tests at room temperature for 5 minutes and repeat stages 1.4 and 1.5. This may enhance the reaction strength in typing red cells of rare phenotypes.

LIMITATIONS

Weaker reactions may be obtained when testing older blood samples.

Red cells that have a positive direct antiglobulin test (DAT) may produce false positive results. The use of BIOSCOT® Monoclonal Control reagent (product code TT) is recommended for detection of such potentially false positive results.

Antigen variant cells may produce unexpected positive or negative reactions with samples previously typed with blood grouping reagents of polyclonal or other cell line-derived monoclonal sources.

False positive or false negative results may occur through contamination of test materials or any deviation from the recommended technique.

PERFORMANCE CHARACTERISTICS

Anti-S (cell line MS-94) blood grouping reagent TJ has been tested by the recommended technique with donor, clinical and neonatal specimens. The sample population represented all major phenotypes. The total number of tests (n), and the calculated sensitivity and specificity for each technique are displayed below:

TECHNIQUE	Anti-S Product Code TJ			
	Sensitivity		Specificity	
	n	%	n	%
Tube	138	100	83	100

Diagnostic Sensitivity: The probability that the device gives a positive result in the presence of the target marker.

Diagnostic Specificity: The probability that the device gives a negative result in the absence of the target marker.

ANALYTICAL PERFORMANCE

This blood grouping reagent(s) exhibited unequivocal positive or negative results by all recommended techniques. Performance was found to be acceptable in terms of repeatability, reproducibility and robustness.

FURTHER INFORMATION

For technical assistance contact: SigmaAldrich.com/techservice

Any serious incident that has occurred in relation to this reagent must be reported to Millipore (UK) Ltd and the competent authority of the Member State in which the user and/or the patient is established.

The summary of safety and performance (SSP) for this device is available in the European database on medical devices (Eudamed) at https://ec.europa.eu/tools/eudamed, where it is linked to the Basic UDI-DI (405325TJBTR5T).

BIBLIOGRAPHY

1. Guidelines for the Blood Transfusion Services in the United Kingdom. 8th Edition 2013. The Stationary Office.
2. Issitt, P.D. and Anstee, D.J. Applied Blood Group Serology 4th Edition, Montgomery Scientific Publications, 1998.
3. AABB Technical Manual 20th Edition,2020.

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SUMMARY OF CHANGES

1. Rebranding & reorganisation of layout.
2. Specification of anticoagulant to be used in specimen collection.
3. Identification of contents of packaging.
4. Update Intended Use section
5. Clarification of drop volume in recommended techniques
6. Addition of limitations statement concerning antigen variant cells.
7. Removal of slide and microplate techniques
8. Update performance characteristics
9. Removal of CTS definition
10. Addition of analytical performance
11. Addition of Further Information section.
12. Addition of technical service contact information.
13. Addition of requirement to contact Millipore (UK) Ltd and competent authority in the case of a serious incident involving this reagent.
14. Addition of information related to summary of safety and performance (SSP).
15. Removal of Introduction and References sections.
16. Addition of Bibliography section
17. Addition of Summary of Changes section.
18. Remove fax number.