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HBS-MedTEK
Simulated Patient Plasma

Intended Use:
Simulated patient plasma (SPP) contains clinically significant IgG red cell antibodies and has been formulated for use in manual indirect testing methods (i.e. tube and gel) in an immunohematology education setting.

Summary and Explanation:
In vitro antibody detection (screening) tests are used to detect the presence of unexpected antibodies in patient and donor sera. Additional in vitro testing allows for the identification of unexpected antibody reactivity.

Principle of the Procedure:
Simulated Patient Plasma is used in an educational setting for the detection and/or identification of unexpected red cell antibodies.

Reagent Description:
SPP is provided as group AB plasma and contains 0.1% (w/v) sodium azide and bovine albumin. Antibody specificity is unique to each product; and all other clinically significant antibodies have been excluded. Refer to product label for antibody specificity. The product has been formulated to react optimally as provided. The product may be blended 1:1 with SPP of one other antibody specificity. For best results, do not blend more than 2 SPPs and do not dilute with any other material.

Included are two vials, labeled anti-A and anti-B which can be used to create group A, B or O plasma.

The format for the expiration date is expressed as YYYY-MM-DD (year-month-day).

Precautions
1. All blood products should be treated as potentially infectious.
2. The human source material used in the manufacture of this product has been tested and found non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV.
3. The source of bovine albumin is either USDA approved or from sources where origin information is available. The donor animals have been inspected and certified disease free and are deemed to have a low TSE (Transmissible Spongiform Encephalopathy) risk.
4. This product contains 0.1% (w/v) sodium azide which is below the national and international thresholds and when used under a normal condition is not chemically hazardous. If this product is discarded in the sink, flush with large volumes of water to prevent buildup of azide.
5. This product is for use in an immunohematology education setting and is not for in vitro diagnostic use.
6. Multiple freeze/thaw storage cycles may affect reactivity. This material may contain fibrin. The presence of fibrin will not adversely affect performance.

Storage
The product should be stored at 2°C - 8°C. Do not dilute. The product is stable until the expiry date stated on the product label. Expiry dating may be extended by freezing the product at -20°C or below.

Procedure:

Materials Provided
Hemo bioscience MedTEK Simulated Patient Plasma

Recommended Techniques:
SPP has been standardized for antiglobulin testing in test tube and column gel phase technologies. Follow the reagent manufacturer's Instruction for Use.

To convert the blood group of the SPP from AB to Group A, B or O follow the chart below.

Desired Blood Group	Anti-A	Ant-B
Group A	**X**	**Add vial**
Group B	**Add vial**	**X**
Group AB	**X**	**X**
Group O	**Add vial**	**Add vial**

Performance Limitations:
1. Contamination with microorganisms or other blood or serum or improper storage may cause false-negative or false-positive results.
2. These reagents are not intended for use in in vitro diagnostic tests.
3. Multiple freeze/thaw cycles may weaken reactivity.

Specific Performance Characteristics:
Prior to release, the product was evaluated and shown to react appropriately with antigen negative and positive red cells specific to the designated antibody specificity. For technical support, contact Hemo bioscience at 1-866-332-2835.

Glossary of Symbols:

Symbol	Definition
	Batch code
	Consult instructions for use.
	Use by YYYY-MM-DD
	Manufacturer

FOR RESEARCH/EDUCATIONAL USE ONLY. NOT FOR IN VITRO DIAGNOSTIC USE.

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