

**Platelet-Antibody Screening Cells &  
Platelet-Antibody Identification Panel Cells Kit &  
Platelet-Antibody Control Plasma/Serum Kit**

**INTRODUCTION**

Neonatal/fetal alloimmune thrombocytopenia (NAIT) due to feto-maternal mismatch for human platelet allo-antigen (HPA) can induce allo-antibodies (anti-HPA) which destroy fetal platelets inducing a severe thrombocytopenia. NAIT has an estimated incidence of 1/1000 pregnancies and *in utero* cerebral bleeds or ventriculomegaly may occur. The screening and identification of allo-antibodies is a mandatory step to prevent and cure these manifestations. Post-Transfusion Purpura (PTP) is another immune mediated destruction of platelets due to anti-HPA allo-antibodies. Platelet Refractoriness (PR) is a clinical situation in which transfused platelets are destroyed by allo-antibodies produced by the recipient. The characterization of these antibodies is a necessary step to provide efficient platelet transfusion.

Monoclonal Antibody-specific Immobilization of Platelet Antigen (MAIPA) is a qualitative technique for platelet antibody detection and/or identification and is considered the gold standard method in the platelet immunology field.

apDia offers all cells, control plasma/serum, reagents and materials necessary to perform the MAIPA procedure. The products are either offered as a complete MAIPA kit or as separate modules allowing to order reagents for defined steps of the MAIPA procedure. If one decides to replace one of the modules by their own reagents, the MAIPA assay should then be validated by themselves using the set of reagents as they will be used.

**REAGENT COMPOSITIONS**



**1. Platelet-Antibody Screening Cells**

**Ref. 900001**

Reagent for the detection of anti-platelet or anti-HLA class I antibodies.

The apDia human thrombocyte based ready-to-use reagents are manufactured by employing a special proprietary process. The standardized screening panel enables sensitive detection of HPA-antibodies. These reagents are especially suitable for the MAIPA procedure. The kit consist of 5 vials of pooled platelets, which contain most of the target antigens for the main known antibodies.

Component	Description	Quantity, Volume	Volume needed for one test	Format
Screening cells <span style="border: 1px solid black; padding: 2px;">SCREEN PLTL</span>	Platelet pool of 6 donors *	5 identical vials 5 x 1 ml	50 µl	RTU

\* Pool of different donor platelets typed for HPA-1, -2, -3, -4, -5, -6, -15  
All donors are of blood group O

**2. Platelet-Antibody Identification Panel Cells Kit**

**Ref. 900002**

Reagents for the identification of anti-platelet antibodies.

The apDia human thrombocyte based ready-to-use reagents are manufactured by employing a special proprietary process. A differentiation panel allows for a reliable identification of the target antigens of the antibodies. These reagents are especially suitable for the MAIPA procedure. The kit contains 6 vials of platelets from single donors. The combination of the antigens of the 6 cells allows identification of the main known antibodies.

**EXAMPLE OF AN ANTIGEN PROFILE (LOT DEPENDENT)**

Component	Description *	Quantity, Volume	Volume needed for one test	Format
Identification platelet 1 IDENT PLTL 1	HPA-1 (a+,b-) HPA-2(a+,b-) HPA-3(a-,b+) HPA-4(a+,b-) HPA-5(a-,b+) HPA-6(a+,b-) HPA-15(a+,b+)	1 vial, 0,65 ml	50 µl	RTU
Identification platelet 2 IDENT PLTL 2	HPA-1 (a-,b+) HPA-2(a+,b-) HPA-3(a+,b+) HPA-4(a+,b-) HPA-5(a+,b-) HPA-6(a+,b-) HPA-15(a+,b+)	1 vial, 0,65 ml	50 µl	RTU
Identification platelet 3 IDENT PLTL 3	HPA-1 (a-,b+) HPA-2(a+,b-) HPA-3(a+,b+) HPA-4(a+,b-) HPA-5(a+,b-) HPA-6(a+,b-) HPA-15(a+,b+)	1 vial, 0,65 ml	50 µl	RTU
Identification platelet 4 IDENT PLTL 4	HPA-1 (a+,b-) HPA-2(a+,b-) HPA-3(a-,b+) HPA-4(a+,b-) HPA-5(a+,b+) HPA-6(a+,b-) HPA-15(a+,b-)	1 vial, 0,65 ml	50 µl	RTU
Identification platelet 5 IDENT PLTL 5	HPA-1 (a+,b-) HPA-2(a+,b-) HPA-3(a-,b+) HPA-4(a+,b-) HPA-5(a+,b-) HPA-6(a+,b-) HPA-15(a+,b-)	1 vial, 0,65 ml	50 µl	RTU
Identification platelet 6 IDENT PLTL 6	HPA-1 (a+,b-) HPA-2(a+,b-) HPA-3(a+,b+) HPA-4(a+,b-) HPA-5(a-,b+) HPA-6(a+,b-) HPA-15(a-,b+)	1 vial, 0,65 ml	50 µl	RTU

\* Six individual platelet cells typed for HPA-1, -2, -3, -4, -5, -6, -15  
All donors are of blood group O

### 3. Platelet-Antibody Control Plasma/Serum Kit

Ref. 900003

Positive and negative control plasma/serum reagents.

The apDia human control plasma/serum kit contains plasma or serum collected from donors tested in MAIPA for the indicated specificity. The kit contains 6 vials of plasma or serum from single donors: 1 vial of an anti-HPA-1a antibody containing plasma/serum, 1 vial of an anti-HPA-5b antibody containing plasma/serum, 1 vial of an anti-HLA antibody containing plasma/serum and 3 vials of negative plasma/serum.

Component	Description	Quantity, Volume	Volume needed per well (test)	Format
Control plasma/serum CONTR 1a	Anti-HPA-1a positive	1 vial, 400 µl	50 µl	RTU
Control plasma/serum CONTR 5b	Anti-HPA-5b positive	1 vial, 400 µl	50 µl	RTU
Control plasma/serum CONTR HLA	Anti-HLA positive	1 vial, 400 µl	50 µl	RTU
Control plasma/serum CONTR NEG	Negative	3 vials, 3 x 400 µl	50 µl	RTU

#### CAUTION AND WARNINGS

These components of human origin were found non-reactive for HBsAg, HCV Ab and HIV (1,2) Ab when tested with licensed reagents. However, since no known test method can assure that infectious agents are absent, all products from human origin should be considered potentially infectious.

#### ADDITIONAL MATERIALS REQUIRED

As required for the selected MAIPA technique and protocol. apDia offers following additional reagent & material kits:

MAIPA Reagents Kit (Monoclonal Antibodies, Cell Wash Buffer, Platelet Lysis Buffer and Microplate)	Ref. 900004
MAIPA ELISA Detection Kit (Coated Microplate, Antibody Conjugate, ELISA Wash Buffer, Chromogen and Stop Solution)	Ref. 900005
Complete MAIPA Kit Consists of a combination of 5 kits: 900001, 900002, 900003, 900004 and 900005 (contains all cells, control plasma/serum, reagents and materials to perform a complete MAIPA test)	Ref. 900006

#### SAMPLE MATERIAL

1. Serum or plasma can be used for indirect MAIPA.
2. Platelets isolated from EDTA whole blood can be used for direct MAIPA.

#### USE AND STORAGE

The apDia thrombocyte reagents are advantageous for standardization, handling and workflow organization in the platelet immunology laboratory. The use of well-characterized thrombocytes offers the ability to standardize the MAIPA procedure: the apDia thrombocyte reagents allow the use of the same batch of typed cells expressing even rare antigen combinations such as HPA-1 (a-,b+) [2.5%] and HPA-5 (a-,b+) [less than 1%] for an extended period of time.



The RTU Platelet-Antibody Screening Cells, RTU Platelet-Antibody Identification Panel Cells Kit and RTU Platelet-Antibody Control Plasma/Serum Kit may be stored at 2-8°C until the expiry date indicated on the label. Reagents should be used within two months after the first opening.

An environment temperature in the lab of 19-25 °C is advised.

## PERFORMANCE CHARACTERISTICS

In a validation study in a French Reference Lab for Platelet Immunology 29 platelet-antibody positive samples were analyzed 3 times (triplicates) by the MAIPA technology using the apDia reagents (ref. 900001, 900002, 900003, 900004 and 900005). In this study a **diagnostic sensitivity** of 97.8 % was obtained (2/(29\*3) tests were found negative).

In the same study using the apDia reagents described above, 326 true platelet-antibody negative samples were analyzed of which 325 were found negative resulting in a **specificity** of 99,7 %.

## LIMITATIONS

MAIPA is considered as the gold standard method for platelet antibody detection and identification.

False positive or false negative results may occur in case of bacterial or other contamination.

In case of spurious or even inconsistent results we recommend to have the sample examined by another laboratory specialized in platelet diagnostics or in a platelet reference laboratory.

MAIPA sensitivity and specificity are high but not 100%. Furthermore to obtain reliable test results it is necessary that the given protocol is strictly followed. The test is designed to detect IgG-type anti-platelet antibodies only.

The apDia platelet products (Ref. 900001 and Ref. 900002) are not useful for screening and identification of the HPA-15 system. This group is included for information purposes only. For HPA-15a and HPA-15b some specific platelets are required to identify the antibodies. Additionally, a specific monoclonal antibody is required.

## BIBLIOGRAPHY

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## PRODUCTS

Platelet-Antibody Screening cells (set of 5 identical tubes)	Ref. 900001
Platelet-Antibody Identification Panel Cells Kit (set of 6 different cells)	Ref. 900002
Platelet-Antibody Control Plasma/Serum Kit (set of 4 controls)	Ref. 900003



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