

FOR RESEARCH USE ONLY IN THE USA
NOT FOR USE IN DIAGNOSTIC PROCEDURES

ALBAclone® ADVANCED PARTIAL RhD TYPING KIT

This insert refers to product Z293U

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

INTRODUCTION

The ALBAclone® Advanced Partial RhD Typing Kit may be used to differentiate partial RhD types, and weak D of types 1 and 2.

The use of a kit for determination of partial RhD types is recommended in the current version of the Guidelines for the Blood Transfusion Services in the United Kingdom. See the reaction profile overleaf for details on the differentiation offered by this kit.

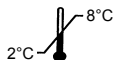
INTERPRETATION OF LABEL SYMBOLS



Batch code



Use by (YYYY-MM-DD)



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



In vitro diagnostic medical device



Consult instructions for use



Harmful



Manufacturer

INTENDED PURPOSE

This ALBAclone® Advanced Partial RhD Typing Kit is for the *in vitro* classification of human partial RhD and weak D types 1 and 2 by indirect agglutination. The product is not suitable for routine RhD typing.

REAGENT DESCRIPTION

The main components of this reagent are derived from the *in vitro* culture of the IgG secreting human/mouse heterohybridomas: LHM76/58, LHM76/59, LHM174/102, LHM50/2B, LHM169/81, ESD1, LHM76/55, LHM77/64, LHM70/45, LHM59/19, LHM169/80 and LHM57/17.

The formulation also contains 1g/L sodium azide.

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.

STORAGE CONDITIONS

The reagent should be stored at 2°C - 8°C. Do not use if turbid. Do not dilute. 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 (Xn), 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 build-up.

CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT IS DERIVED WAS FOUND NON-REACTIVE FOR HBsAg, ANTI-HIV 1/2 AND ANTI-HCV. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS DISEASE. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT. This reagent is for *in vitro* professional use only.

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected by aseptic technique with or without an anticoagulant. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at 2°C - 8°C. Blood specimens exhibiting gross haemolysis or contamination should not be used. Clotted samples or those collected in EDTA should be tested within seven days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiry date.

TEST PROCEDURES

This reagent has been standardised for use by the techniques described below and therefore its suitability for use in other techniques cannot be guaranteed.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- NISS (PBS pH 7.0 ± 0.2)
- LISS
- Reagent red cells suitable for the control of Anti-D
- 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Polyspecific Anti-Human Globulin/Anti-Human IgG

RECOMMENDED TECHNIQUES

LIS, 37°C Indirect Antiglobulin

- Add 2 volumes of blood grouping reagent to a 12 x 75mm glass tube.
- Add 2 volumes of 1.5-2% LISS suspended cells.
- Mix the test well and incubate for 15 minutes at 37°C
- Wash the test 4 times with a large excess of PBS pH 7.0± 0.2 (eg 4ml of PBS per 12 x 75mm tube).

NOTE: (i) allow adequate spin time to sediment the red cells.
(ii) ensure that most of the residual saline is removed at the end of each wash to leave a 'dry' cell button.

- Add two drops of the anti-human globulin reagent to each tube.
- Mix thoroughly.
- Centrifuge at 1000g for 10 seconds or at a suitable alternative g force and time.
- Gently shake the tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

NIS, 37°C Indirect Antiglobulin.

- Add 2 volumes of blood grouping reagent to a 12 x 75mm test tube.
- Add 1 volume of 2-3% NISS suspended red cells.
- Mix the test well and incubate for 15 minutes at 37°C.
- Wash the test 4 times with a large excess of PBS pH 7.0± 0.2 (eg 4ml of PBS per 12 x 75mm tube).

NOTE: (i) allow adequate spin time to sediment the red cells.
(ii) ensure that most of the residual saline is removed at the end of each wash to leave a 'dry' cell button.

- Add two drops of the anti-human globulin reagent to each tube.
- Mix thoroughly.
- Centrifuge at 1000g for 10 seconds or at a suitable alternative g force and time.
- Gently shake the tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

QUALITY CONTROL

Quality control of reagents is essential and should be performed with each series of groups and with single groups. It is recommended that as a minimum at least one example of red cells of the phenotype R₁r be used as a positive control and rr red cells be used as a negative control.

PERFORMANCE LIMITATIONS

•Weak D samples may react with all kit components to varying degrees due to variation in antigen site density.

•Driblocks and water baths promote better heat transfer and are recommended for 37°C tests, particularly where the incubation period is 30 minutes or less.

•The expression of certain red cell antigens may diminish in strength during storage, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.

•Tube tests should be read by a 'tip and roll' procedure. Excessive agitation may disrupt weak agglutination and produce false negative results.

•It is important to use the recommended g force during centrifugation as excessive centrifugation can lead to difficulty in re-suspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

•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.

•Any sample that does not fit into this reaction profile requires further investigation. Such samples may be referred to Alba Bioscience for further investigation.

•Direct antiglobulin test positive samples will react by the indirect antiglobulin test irrespective of their RhD status.

CAUTION

This product or any of its components are NOT suitable for routine RhD typing of donor/patient samples.

SPECIFIC PERFORMANCE CHARACTERISTICS

The reaction profile overleaf applies to all current and previous batches of the ALBAclone® Advanced Partial RhD Typing Kit. We may update the reaction profile between batches – check our website for the most up-to-date version of the reaction profile, supplementary information and recent findings. www.albabioscience.co.uk

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Z293PI/04/Q1



QUOTIENT
BIODIAGNOSTICS

Reaction Profile of the ALBAclone[®] Advanced Partial RhD Typing Kit, Z293U

SAMPLE DETAILS			
Name:		Sample Identification:	
Address:		Hospital:	
		Ward:	Unit No:
		Diagnosis:	
D.O.B:	Additional Information:		

Lot No: _____	CE
Expiry Date: _____	

Check our website for the most up-to-date version of the reaction profile, supplementary information and recent findings. www.albabioscience.co.uk

Kit ID	Anti-D Cell Line	Weak D Type 1 and 2 ^o	DII & DNU	DIII	DIV	DV*	DCS	DVI	DVII	DOL	DFR	DMH	DAR [†]	DAR-E	DHK [‡] & DAU-4	DBT	Ro ^{Har §}	Test Results				
																		Pos Cont.	Neg Cont.			
A	LHM76/58	+	+	+	+	+/0	+	0	+	+	+	+	+	0	0	0	(+)/0					
B	LHM76/59	+	+	+	0	+	+	+	+	+	+	+	+	+	+	0	0					
C	LHM174/102	(+)/0	+	+	0	0	+	0	+	0	0	+	0	0	0	0	0					
D	LHM50/2B	+	+	+	+	+	+	0	+	+	+	+	+	+	+	0	0					
E	LHM169/81	+	+	+	0	0	+	0	+	+	+	+	0	0	0	0	0					
F	ESD1	+	+	+	0	+	+	+	+	+	+	+	+	+	+	0	0					
G	LHM76/55	+	+	+	0	+	+	+	+	+	+	+	+	+	+	0	0					
H	LHM77/64	+	0	+	0	+	+	+	+	+	+	+	+	+	+/0	0	0					
I	LHM70/45	(+)/0	+	+	0	0	0	0	+	0	0	0	0	0	0	0	0					
J	LHM59/19	+	+	+	+	+	+	0	0	0	0	(+)	0	(+)	+	+	0					
K	LHM169/80	+	+	+	+	+	+	0	+	+	+	+	+	+	0	0	0					
L	LHM57/17	+	+	+	+	+	0	0	+	+	0	+	+	0	0	+	0					

^oRefer to website for supplementary information.

*Within the DV category there are currently 8 different types. The majority of DV's used in the evaluation of this kit were categorized as DVa. Other DV's may vary in their reaction profile with this kit.

[†]With kit components C, E and J, DAR homozygotes have been shown to give positive reactions.

[‡]DHK may also be referred to as DY0.

[§] Possible Ro^{Har} samples can be confirmed by testing against Alba Bioscience anti-D alpha, product code Z031U.

Bibliography

Wagner *et al.*, (2000). Weak D alleles express distinct phenotypes. *Blood*, 95, 2699-2708.

Reid, M.E. and Lomas-Francis, C. (1997). *The Blood Group Antigen Facts Book*. Academic Press, Harcourt Brace & Company, Publishers.

UK Blood Transfusion Services. (2005). *Guidelines for the Blood Transfusion Services in the United Kingdom*. 7th Edition. The Stationary Office, Norwich.

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