

MeriSera Anti-H Lectin

ULEX EUROPAEUS LECTIN FOR SLIDE AND TUBE TEST

Product Code: AHLSER-01

INTRODUCTION

The H antigen is part of the Hh system and is found on all red cells except those of Oh (hh) Bombay phenotype, which is extremely rare. H is the precursor of A and B and so group A and B people have less H than O people. The order of reactivity of Anti-H with red cells of various ABO groups is: **O>A₂>A₂B>B>A₁>A₁B.**

PRINCIPLE

The reagent will cause agglutination of test red cells, that carry the H antigen, No agglutination generally indicates the absence of the H antigen.

REAGENT COMPOSITION

This ready to use reagent is an extract of *Ulex europaeus* seeds. It contains a phytohemagglutinin, which is virtually specific for the H antigen on human red blood cells.

Kit contain following Reagent:

No	Reference No	Name of Product	Pack Size
1	AHLSER-01	MeriSera Anti-H Lectin	1 x 5 ml

MATERIALS REQUIRED

Glass slides, test tubes, pasture pipettes, isotonic saline (0.9% NaCl solution), centrifuge, timer, applicator sticks, and Sodium hypochlorite (1%).

STORAGE OF TEST KIT

Test kits should be stored at **2-8°C** upon receipt. Sodium azide is added to the reagent at 0.1% concentration as preservative. The test kit may be used till the time of the expiry date mentioned. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. **Do not freeze.**

SAMPLE COLLECTION AND STORAGE

Do not use haemolysed samples. Samples should be collected with a suitable anticoagulant in a sterile container and should be tested immediately. If testing is delayed, blood should be stored at 2-8°C. EDTA and citrate samples should be typed within 48 hours. Samples collected into ACD, CPD or CPDA-1 may be tested up to 35 days from the date of withdrawal. Clotted samples should be used within 24 hours of collection.

PRECAUTIONS AND WARNINGS

1. Test for *in-vitro* diagnostic use only and should be run by competent and trained person only.
2. Over centrifugation could lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and determine the time required for achieving the desired results.
3. After usage the reagents should be immediately recapped and stored at 2-8°C.
4. The reagent contains 0.1% sodium azide as a preservative. Avoid contact with eye, skin & mucosa.
5. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded
6. Always wear hand gloves while performing the test. Avoid re-using gloves or use of washed gloves.

7. Do not smoke, eat and drink in the testing area.
8. Do not use haemolysed specimen for testing.
9. Do not use the reagent beyond expiry date.
10. Do not pipette by mouth.
11. All the materials used in the assay and samples should be decontaminated in 1% sodium hypochlorite. They should be disposed of in accordance with established safety procedure.
12. Spills should be decontaminated promptly with sodium hypochlorite or any other suitable disinfectant.
13. Wash hands thoroughly with soap or any suitable detergent, after the use of kit. Consult a physician immediately in case of accident or contact with eyes.

CONTROLS AND ADVICE

1. It is recommended a positive control and a negative control to be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. In the **Recommended Techniques** one volume is approximately 50µl when using the vial dropper provided.
3. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.
4. User must determine suitability of the reagent for use in other techniques.

TEST PROCEDURE

Bring reagent and blood specimen to room temperature before testing. Blood grouping should be performed at room temperature by:

1. **Slide method**
2. **Tube method**

1.Slide method:-

1. Place a one drop (50µl) of reagent on a clean labelled glass slide at room temperature (18-25°C).
2. Add one drop (50µl) of whole blood to be tested on the slide.
3. Mix well using a clean applicator uniformly.
4. Slowly tilt the slide back and forth and observe for agglutination macroscopically at two minutes.

2.Tube method :

1. Prepare a 5% suspension of the red cells to be tested in isotonic saline.
2. Place one drop (50µl) of reagent into correspondingly labelled test tubes.
3. Add one drop (50µl) of the test red cell suspension, mix well and incubate at room temperature (18-25°C) for 5 minutes.
4. Gently shake tube to mix the contents thoroughly.
5. Centrifuge for 1 minute at 1000rpm.
6. Gently re-suspend the cell button, observing for agglutination macroscopically.
7. For specificity, observe all the negative tubes under the microscope for clear negative reaction.

INTERPRETATION OF RESULTS:

Agglutination is a positive test result and indicates the presence of H antigen.

Do not interpret peripheral drying or fibrin strands as agglutination.

No agglutination is a negative test result and indicates the absence of H antigen.

TROUBLE SHOOTING:

	Cause/Error	Remedy
1	Contaminated Blood specimen or reagent	--Make sure that there is no contamination of blood specimen or reagent. -- Use clean slide and tubes for testing.
2	Drying in slide test	-- Do not read the result after 2 minutes.
3	Clotting of blood	-- Test the sample immediately if anticoagulant is not added to the sample

False Negative

	Cause/Error	Remedy
1	Contaminated Blood specimen or reagent	--Make sure that there is no contamination of blood specimen or reagent. -- Use clean slide and tubes for testing. -- Do not read the result after 2 minutes.

Weakly/ Delayed Reaction

	Cause/Error	Remedy
1	Prolonged storage of red blood cells	-Store the blood sample with anticoagulant at 2-8°C for less than 30 days.
2	Expired Reagent	-- Check the expiry date on the reagent bottle.

DISCLAIMER

1. The user is responsible for the performance of the reagent by any method other than those mentioned in the **Recommended Techniques**.

2. Any deviations from the **Recommended Techniques** should be validated prior to use.

LIMITATIONS

1. Anti-H may react with Tn-polyagglutinable or Cad-positive cells.

2. Stored blood may give weaker reactions than fresh blood.

3. False positive or false negative results may also occur due to:

→ Contamination of test materials

→ Improper storage, cell concentration, incubation time or temperature

→ Improper or excessive centrifugation

→ Deviation from the recommended techniques

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer limits the warranty to the test kit, in as much as that the test kit will function as an in vitro diagnostic assay within the limitations and specifications as described in the product instruction-manual, when used strictly in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to for claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application thereof.

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The reagent has been characterized by all the procedures mentioned in the **recommended technique**.

2. Prior to release, each lot of MeriSera Anti-H Lectin reagent is tested by the **Recommended Technique** against a panel of antigen-positive red cells to ensure suitable reactivity.

3. The Quality Control of the reagent was performed using red cells that had been washed twice with PBS or Isotonic saline prior to use.

WARRANTY

This product is designed to perform as described on the label and pack insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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