HEMA TEST

IVD *For In-Vitro and professional use only*

Store at 2° to 8° C

INTRODUCTION

HEMA TEST is used for plasma ABO blood group determination.

PRINCIPLE

The manual technique employed, on plate or in tube, utilizes the principle of hemagglutination. Red blood cells bearing an antigen agglutinate in the presence of test plasma containing the corresponding antibody.

ABO group determination is defined both my demonstration of antigens A and/or B on both surface of human red blood cells and by presence or absence or anti-A and/or Anti-B antibodies in the plasma.

It is thus appropriate to identify the erthrocytic antigens using know anti-A , anti-B and anti-AB reagents (red blood cell tests), then to confirm the preceding results by checking the presence of corresponding antibodies in the plasma from the test blood using HEMATEST A1, B , and possibly , HEMATEST A2 and O (Plasma test).

MATERIAL

HEMATEST are prepared from a mixture of human red blood cells of known groups A1 RH-1, B RH-1, A2 RH-1 and O RH-1.

The red blood cells prepared in 5% ready for use suspension in a storage solution and are packaged in 5 mL vials fitted a calibrated dropper.

REAGENTS AND MATERIAL NECESSARY

- Glass test tubes, 10 or 25x75 mm, tube rack.
- Stirrer mixer.
- Opaline plate.
- Precision automatic adjustable pipettes.
- Centrifuge with a relative force of 100-1200 g.
- Blood samples with known phenotypes of group A,B,O .

PRECAUTIONS

- HEMATEST is a human origin which have been tested and found to be negative for anti-HIV 1 and anti-HIV 2 antibodies, anti-HCV, HBsAg and Syphilis.
- Wear gloves and handle samples of human origin with caution.
- Test materials and samples should be discarded properly in a biohazard container.
- Wash hands and the test table top with water and soap once the testing is done.

STORAGE

- The Reagent should be stored refrigerated between 2 °C and 8 °C.
- Never freeze or expose to elevated temperature.

PROCEDURE

1. PLATE TECHNIQUE AT ROOM TEMPERATURE (+18..+25 ℃):

1. Gently shake each HEMA TEST in order to homogenize the suspension.
2. On a rigorously clean plate, using a vial dropper, apply 1 drop of each HEMA TEST.
3. Take 100 of test plasma and apply next to each drop of HEMA TEST taking care not to create contact between the drops.
4. Mix the plasma and HEMA TEST using a spiral movement with the end of a stirrer in order to create a regular lozenge of diameter 2 to 3 cm.
5. Hold the plate and give it a rolling movement for 3 minutes while macroscopically observing the possible appearance of agglutinates.
6. Read the reactions immediately.

2. TUBE TECHNIQUE AT ROOM TEMPERATURE (+18..+25 ℃):

1. Gently shake each HEMA TEST in order to homogenize the suspension.
2. Using the vial dropper, transfer 1 drop of each HEMA TEST to each tube.
3. Add 100 of plasma to each tube.
4. Shake to homogenize the mixture.
5. Centrifuge at 55 g for 1 minute.
6. Macroscopically read the tubes while shaking gently to detach the red blood cell pellet.
7. Note any appearance of agglutinates.

SAMPLES –CONTROLS

BLOOD SAMPLE TO BE TESTED

Blood collected in anticoagulant EDTA, Heparin or Citrate, in stopped sterile tube stored between 2 and 8 °C must be examined with 48 hours insofar as no sign of hemolysis is visible.

At this time of the test, centrifuge the blood sample at 1200 g for 3 minutes.

BLOOD SAMPLES WITH KNOWN GROUP PHENOTYPES

The analytical system must be validated using sets of samples with known phenotypes of group A, group B and group O.

Use of those samples or HEMA CQI enables detection of anomalies (handling, reagents, materials and environment) and implementation of corrective actions.

INTERPRETATION

- If agglutination occurs (the blood cells form one or several clumps), the reactions is positive and the antibody corresponding to the HEMA TEST is present in the plasma.
- If there is no agglutination (the red blood cells remain in homogeneous suspension), the reaction is negative and the corresponding antibody is not present in the test plasma.
- The analytical system may be validated using samples of known phenotypes.
- The ABO group of a subject can only be unambiguously determined if there is strict concordance between the results of the blood cell test and those of the plasma test.
  If there is discordance, do not report a result and pursue identification of the blood group in compliance with current recommendations and protocols or forward the sample to an expert laboratory.
  The 'auto' control,'allo' control and 'reagent' control, and clinical context may help elucidate the anomaly.
  'Auto' control: under the same conditions, test the subject's plasma vis-à-vis his own red blood cells.
  'Allo' control: under the same conditions, test the subject's plasma vis-à-vis a panel of test known O red blood cells (detection of anti-erythrocytic antibodies other than anti-A or anti-B).
  'Reagent' control: under the same conditions, test the subject's red blood cells vis-à-vis the negative control.
  The use of HEMA TEST A2 and O may evidence an anomaly in the plasma determination of ABO group.

LIMITATIONS OF THE METHOD

Only qualified personal should use the reagent.

It is imperative to use the calibrated dropper provided in the IVDMD vial to dispense a reagent drop.

The reaction must be read immediately after centrifuge and re-suspension.

It is imperative to work with clean equipment and non-contaminated products (bacterial or other contamination).

The following points must be scrupulously observed:

- Storage conditions and expiry date,
- The procedure,
- Calibration of recommended equipment.

PERFOMANCE DATA

The red blood cell concentration used in the preparation of HEMA TEST are collected and controlled by the Atlas medical in compliance with current regulations for qualification of those products for transfusion use and also in compliance with all French applicable texts issued by French competent authorities, particularly:

- The provisions of the decrees relating to Good Practices for the Preparation of libile blood products relating to Good Practices for donation qualification, amended by the current diseases.
- The current decree relating to laboratory tests and screening tests for transmissible diseases effected on blood samples and their constituents.

A false-positive may occur if the subject tested possesses clot agglutinins.

The intensity of the reactions obtained may depend on the anti-A and/or anti-B antibody levels of the test subject.

Weak or even negative reaction inducing discordance between the red blood cell and plasma tests may be observed in neonates and immunocompromised subjects.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry