SpermMar Test IqA

A qualitative beads test for detection of Sperm Antibodies of the IgA class

Preservative: Sodium azide 0.09%. Store at 2° to 8° C - Do Not Freeze For in vitro diagnostic use only. Reagent for professional use only.

INTENDED USE

The SpermMar Test IgA is a diagnostic kit for detecting antisperm antibodies of the IgA class in human semen. The presence of antisperm antibodies can interfere with sperm function and zona binding and the acrosome reaction.

GENERAL INFORMATION

The presence of sperm antibodies reacting with antigen(s) on the spermatozoa is considered as typical and specific fo

on the spermatozoa is considered as typical and specific for immunological infertility (1,3,22,24). These antibodies are found in approximately 8% of infertile men (13). Antisperm antibodies belong to different immunological classes, but only those of the IgG and the IgA class are clinically relevant (18). The former display cytotoxic effects and are adequately detected on spermatozoa or in serum with the SpermMar Test IgG. Antisperm antibodies when bound to complement (3.0 fibe Ind class, which mainly have bound to complement C3 of the IgA class, which mainly have agglutinating properties (14), rarely occur without antibodies of the IgG class (6), but their meaning for male infertility may be more important. Indeed, patients combining speri may be more important. Indeed, patients combining sperm antibodies of the IgA class with IgG antibodies, or presenting IgA antibodies alone have very little chance of impregnating their partner through natural ways (6,20). Hence, detection of antibodies of the IgA class is of the utmost importance both for diagnosis and prognosis (21). The bulk of the IgA class antisperm antibodies are secreted by the accessory sex glands (23). They are present on the spermatoza and sometimes in seminal plasma, but usually

spermatozoa and sometimes in seminal plasma, but usually are absent in serum. Therefore, testing for antisperm ant bodies of the IaA class on serum is not recommended (18). It may be considered to search for sperm antibodies of the IgA class in seminal plasma, in cases with low sperm concentra-tion or motility, although the possible clinical meaning of these antibodies is questionable.

The direct SpermMar Test IgA is a test for the detection of sperm coating antibodies, performed on either fresh spermatozoa, or spermatozoa which are isolated from seminal plasma by one cycle of suspension, centrifugation and resuspension in medium. These spermatozoa are mixed with the beads which are coated with antihuman anti-loA. The formation of mixed applutinates of motile spermatozoa with beads indicates the presence of IgA antisperm antibodies on the spermatozoa (1,5,9,10,17).

PRODUCT ORDER CODES

SpermMar Test IgA single kit – 50 tests SpermMar Test IgA complete kit – 50 tests

MATERIALS INCLUDED WITH THE TEST

- » 1 vial containing 0.7ml SpermMar Test IgA beads Microscope slides 76x26 mm*
- Cover glasses 24x40 mm
- Microcapillary pipettes calibrated at 10 microlitres*
 Rubber bulb*

A certificate of analysis and MSDS are available on request or can be downloaded from out website (www.fertipro.d

MATERIALS NOT INCLUDED WITH THE TEST

- » Light microscope (with 400x to 600x magnification
- bright field, dark field or phase contrast)

 » Non-spermicidal condom

DIRECTIONS FOR USE



demonstration video (download via link on our website or scan barcode).

SPECIMEN COLLECTION & PREPARATION

Semen collection by masturbation is preferred. Where particular circumstances discourage collection by masturbation, specific plastic condoms are available from FertiPro for semen collection. Ordinary condoms should not be used for semen collection because they may interfere with the motility and viability of the spermatozoa. Ideally, semen should be examined within 1 hour after ejaculation.

REAGENT PREPARATION

The SpermMar Test IgA Latex particles are ready to use, however, they should be thoroughly mixed before use to provide a homogeneous suspension.

DIRECT SPERMMAR TEST IGA FOR THE DETECTION OF ANTISPERM ANTIBODIES OF THE IGA CLASS ON HUMAN SPERMATOZOA

- 1. Allow reagents and specimens to adjust to room
- temperature.
 2. On a microslide place :
- » 10 microlitres of fresh semen

» 10 microlitres of fresh semen » 10 microlitres of SpermMar Test IgA Latex particles This can be done by means of the 10 microlitres capillary pipettes, if provided in the kit. Note: To use the microcapillary pipettes, insert the end of the pipette marked with a heavy black line into the rubber bulb (approximately 5 mm). Allow pipette to fill by capillary action to the first mark (10 microlitres). Do not draw liquid into the bulb. Place tip of finger over the top of the bulb. Holding the bulb between thumb and middle finger, gently squeeze the bulb to expet the liquid from the pipette. queeze the bulb to expel the liquid from the pipette

3. Mix the sample and the latex reagent 5 times with the edge of a cover glass.

- The cover glass is put on the mixture and the mixture is observed under a light microscope using a 400x to 600x magnification. The use of phase contrast or dark field illumination may facilitate reading the slide.
- field illumination may facilitate reading the slide.

 Read the result after 3 minutes. Observe for Latex
 particles attached to the motile sperm. Count 100
 sperm cells to determine the percentage of reactive
 sperm. Read again after 10 minutes.

 Note: Keep the preparation in a damp chamber (e.g. a petri
 dish containing a moistened piece of filter paper).

 The diagnosis of immunological infertility is suspected
 when 10,33% of the motils spermators are attached to
- when 10-39% of the motile spermatozoa are attached to latex particles; if 40% or more of the spermatozoa are attached, immunological infertility is highly probable

INTERPRETATION OF RESULTS

When the test is performed properly, the absence of anti-sperm antibodies will be shown by freely moving sperma-tozoa not covered by Latex particles. The Latex particles may, but usually do not agglutinate among themselves. In the presence of antisperm antibodies the spermatozoa will react with the particles and one, later several particles will othable to all or a prescription of the media propriet several particles. will attach to all or a proportion of the motile spermatozoa. The percentage of motile spermatozoa showing this mixed agglutination is directly related with the severity of the immunological reaction

immunological reaction.

In general, the proportion of motile spermatozoa reacting in the SpermMar Test IgA is smaller than that reacting in the SpermMar Test IgA, but the contrary may occasionally occur (12). In rare cases there is a positive reaction in the SpermMar Test IgA in the absence of any reaction in the SpermMar Test IgA, indicating the presence of secretory atthorities of the IgA Cases without artificialized for the IgA. antibodies of the IgA class without antibodies of the IgG class. Occurrence of mixed agglutination reaction of 40% or more in semen indicate a positive reaction to the SpermMa

LIMITATIONS OF THE METHOD

The direct SpermMar Test IgA can only be performed if motile spermatozoa are present in the semen sample. Samples with very low sperm concentration or motility may yield false

PERFORMANCE CHARACTERISTICS

Several hundreds of semen samples have been tested Several hundreds of semen samples have been tested with the direct mixed antiglobuline reaction and the direct SpermMar test for IgG. The results were similar in 97% of the cases. In 3% of the cases the SpermMar test detected antibodies whereas the mixed antiglobulin reaction test using coated red blood cells was negative. In such cases the proportion of spermatozoa reacting in the SpermMar test usually was low (14). The results of the SpermMar Test IgA were proven accurate after comparison with immunofluorescence and nephelometry. cence and nephelometry.

REAGENT STORAGE

When stored properly, SpermMar Test IgA reagent is stable for 12 months from date of manufacturing. SpermMar Test IgA reagent must be stored at between 2° and $8^{\circ}\mathrm{C}$ when not in use. D0 NOT FREEZE REAGENT. Suitable for transport or short term storage at elevated temperatures (up to 5 days at $37^{\circ}\mathrm{C}$).

WARNINGS AND PRECAUTIONS

Handle all specimens as if capable of transmitting HIV or hepatitis. Always wear protective clothing when handling specimens. SpermMar Test IgA contains 0.1% Bovine Serum Albumin of US origin.

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TECHNICAL SUPPORT



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