EN

SpermMar Test IgA

IVD

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MATERIAL INCLUDED

Catalogue number

SpermMar Test IgA – Single kit

SPMA_S	SpermMar Test IgA Single kit 50 tests

SpermMar Test IgA – Complete kit

SPMA_C	SpermMar Test IgA Complete kit 50 tests

CUSTOMER-TECHNICAL SUPPORT

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CE 2797

SpermMar Test IgA

For in vitro diagnostic use only.
Reagent for professional use only.

INTRODUCTION

As sperm does not come into contact with the blood circulation, the male reproductive system contains no antisperm antibodies in normal conditions. However, when the blood-testis barrier is breached, the immune system can detect mature sperm as antigenic and form antisperm antibodies that cause sub- or infertility. Antisperm antibodies belong to two immunological classes: immunoglobulin (Ig)A and IgG antibodies. Antisperm IgA antibodies are clinically associated with immunological infertility (1-3), and screening can therefore provide help in assessing the male fertility.

INTENDED USE

The SpermMar Test IgA is a semi-quantitative, non-automated, diagnostic kit for detecting antisperm antibodies of the IgA class on spermatozoa in human semen. It is a rapid, easy-to-use microscopic test.
The SpermMar Test IgA can be performed on fresh, untreated human semen provided that it contains motile spermatozoa. The SpermMar Test IgA can be used as an aid in the diagnosis and management of male infertility.

PRINCIPLE OF THE TEST

The SpermMar Test IgA is performed on fresh untreated spermatozoa. The spermatozoa are mixed with latex particles which have been coated with anti-human IgA. The formation of mixed agglutinates of motile spermatozoa with latex particles indicates the presence of IgA antisperm antibodies on the spermatozoa.

MATERIALS INCLUDED WITH THE TEST

SpermMar Test IgA Single kit:
- 1 vial containing 0.7 ml SpermMar Test IgA latex particles

SpermMar Test IgA Complete kit:
- SpermMar Test IgA Single kit
- Micro Slides 76 x 26 mm
- Cover-glasses 24 x 40 mm
- Microcapillary pipettes calibrated at 10 microliters
- Rubber bulb

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

MATERIALS REQUIRED, BUT NOT PROVIDED

- Light microscope (with 400x to 600x magnification, bright field, dark field or phase contrast)
- Non spermicidal condom (if required)
- In case the SpermMar Test IgA Single kit is purchased: micro slides, cover glasses, (capillary) pipettes

METHOD

Scan barcode (or download link on www.fertipro.com) to view the demonstration video.

Specimen collection and preparation
Standard semen collection containers should be used, typically in polypropylene and sperm survival/sperm motility tested, when semen is collected by masturbation. Non semen-toxic plastic condoms should be used when semen collection by masturbation is not possible. Keep the semen collection container at room temperature before adding the semen sample in order to avoid large changes in temperature that may affect spermatozoa. Ideally, semen should be examined within 1 hour after ejaculation.

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

Method SpermMar Test IgA
1. Allow the reagents and specimens to adjust to room temperature.
2. Vortex or thoroughly mix the SpermMar Test IgA Latex Particles.
3. On a micro slide, place:
   - 10 µl of fresh untreated semen
   - 10 µl of SpermMar Test IgA Latex Particles

This can be done by means of the provided 10 microliters capillary pipettes (complete kit only).

Note: *To use the microcapillary pipettes, insert the end of the pipette marked with the heavy black line into the rubber bulb (approximately 5 mm). Allow the pipette to fill by capillary action to the first mark (10 microliters). Do not draw liquid into the rubber bulb. Holding the bulb between the thumb and the middle finger, gently squeeze the bulb to expel the liquid from the pipette.*

4. Mix the sample and the latex reagent with the edge of a cover glass.
5. Put the cover glass on the mixture and observe the mixture under a light microscope using a 400x or a 600x magnification. The use of a phase contrast or dark field illumination may facilitate reading of the slide.
6. Read the result after 3 minutes. Observe for latex particles attached to motile sperm. Count 100 spermatozoa to determine the percentage reactive sperm. If no attachment of latex particles to sperm is observed, 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).*

INTERPRETATION OF THE RESULTS

When the test is properly performed, the absence of sperm antibodies will be shown by freely moving spermatozoa not covered by latex particles. The latex particles may, but usually do not, agglutinate among themselves. In the presence of sperm antibodies however, the spermatozoa will react with the particles and 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. Occurrence of the mixed agglutination reaction of 40% or more in semen indicates a positive reaction to the SpermMar Test IgA.

LIMITATIONS OF THE METHOD

The SpermMar Test IgA can only be performed if motile spermatozoa are present in the semen sample. Samples with very low sperm concentration or poor motility cannot be evaluated, since 100 motile spermatozoa must be assessed following incubation with the reagents. Immotile cells should not be counted.
The test can help in the management of male infertility, however additional tests should confirm the diagnosis of infertility.

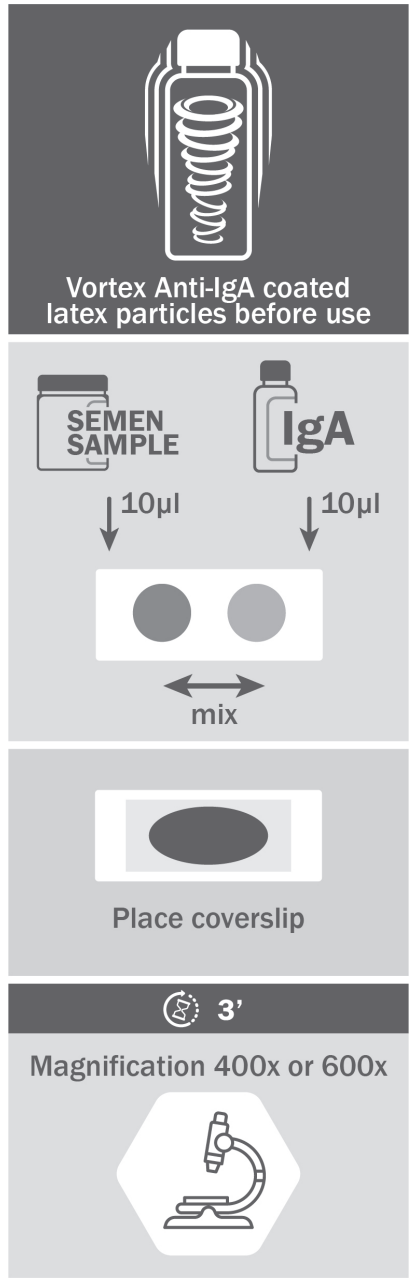
PERFORMANCE CHARACTERISTICS

The SpermMar Test IgA shows a good positive correlation with the direct Immunobead Test (4, 5). Furthermore, an excellent positive correlation was found between the SpermMar Test IgA and flow cytometric detection of IgA antibodies (6).

REPEATABILITY AND REPRODUCIBILITY

Repeatability and reproducibility were assessed using samples with different severities of immunological reaction. The CV_{intra} and CV_{inter} of the SpermMar Test IgA are 5.10% and 5.37% respectively, which is well below 15%, indicating an acceptable repeatability and reproducibility for the SpermMar Test IgA.

Graphic presentation of the protocol:



STORAGE/DISPOSAL

- One kit of SpermMar Test IgA is intended for 50 individual tests that can be performed spread over the shelf life. After each individual test, all used reagents and materials should be discarded. Close reagent bottles well after each use and store at 2-8 °C. Even after opening, the SpermMar Test IgA reagent is stable for 12 months from the date of manufacturing.
- Do not use after expiry date.
- Do not freeze.
- The reagent needs to be disposed in accordance with local regulations for disposal of medical devices taking into account that the devices contains animal derived substances.

WARNINGS AND PRECAUTIONS

All human, organic material should be considered potentially infectious. 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, which is certified by a EDQM Certificate of Suitability. Furthermore, the product meets European requirements for treated technical blood products.
SpermMar Test IgA latex particles are coated with a monoclonal rat anti-human IgA.
Contamination is prevented by the addition of sodium azide as a preservative (< 1g/l).
Any serious incident (as defined in the European In Vitro Diagnostic Medical Device Regulation 2017/746) that has occurred should be reported to FertiPro NV and to the competent authority of the EU Member State in which the user and/or patient is established.

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SYMBOLS GLOSSARY

Symbols as defined in ISO 15223	
REF	Catalogue number
LOT	Batch code
	Consult instructions for use
	Manufacturer
IVD	In Vitro Diagnostics
°C	Temperature limit
	Use-by date
	Caution
BIO	Contains biological material of animal origin
Σ 50	Contains sufficient for 50 tests

Symbol as defined in IVDR 2017/746	
CE 2797	CE marking by Notified Body 2797

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