INTENDED USE
The SpermMar Test IgG is a diagnostik kit for detecting antibodies against the IgG class in human semen or serum. The direct SpermMar Test IgG can be performed as an仲裁or of the indirect SpermMar Test IgG. This kit contains all reagents and instructions necessary for the detection of sperm antibodies. The SpermMar Test IgG Positive and Negative Controls are ready-to-use and can be used for the indirect SpermMar Test IgG.

GENERAL INFORMATION
The presence of sperm antibodies reacting with antigens on the spermatozoon is considered as typical and specific for immunological infertility (2, 4, 10). These antibodies are found in approximately 8% of infertile men (13). Sperm antibodies belong to two immunological classes; IgA and IgG antibodies. There are some data indicating that IgA is to be more clinically important than IgG antibodies. However, IgA antibodies rarely occur without IgG antibodies. Therefore, testing for IgG antibodies is sufficient as a routine screening method (9, 14).

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 themselves will form growing agglutinates thus proving the reactivity of the reagents. In the presence of sperm antibodies however, the spermatozoa will be partially covered by latex particles. In some cases the spermatozoa might even be immobilized by the massive amount of adherent latex particles. In the direct SpermMar Test IgG, the diagnosis of immunological infertility is suspected when 10-20% of the spermatozoa are covered by latex particles; if 40% or more of the spermatozoa are covered, immunological infertility is highly probable. Additional tests should confirm the diagnosis. Whenever a positive result is obtained, the indirect SpermMar Test IgG should be performed. In the indirect SpermMar Test IgG, the occurrence of 40% or more reaction between the coated latex particles and motile spermatozoa is recommended as the lower limit of significant activity.

LIMITATIONS OF THE METHOD
The direct SpermMar Test IgG can only be performed if motile spermatozoa are present in the semen. Poor motility may yield false negative results in those cases which are covered by latex particles; if 40% or more of the spermatozoa are covered by latex particles, immunological infertility is highly probable. Additional tests should confirm the diagnosis. Whenever a positive result is obtained, the indirect SpermMar Test IgG should be performed. In the indirect SpermMar Test IgG, the occurrence of 40% or more reaction between the coated latex particles and motile spermatozoa is recommended as the lower limit of significant activity.

PRECAUTIONS
The SpermMar Test IgG is a diagnosis kit for detecting antibodies against the IgG class in human semen or serum. The direct SpermMar Test IgG can be performed as an arbitration of the indirect SpermMar Test IgG. This kit contains all reagents and instructions necessary for the detection of sperm antibodies. The SpermMar Test IgG Positive and Negative Controls are ready-to-use and can be used for the indirect SpermMar Test IgG.

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SpermMar Test IgA

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

**Intended Use**

The SpermMar Test IgA is a diagnostic kit for detecting anti-sperm antibodies of the IgA class in human semen. The presence of anti-sperm antibodies can interfere with sperm function and ultimately affect the success of conception.

**General Information**

The presence of sperm antibodies resulting with antisperm antibodies is considered as positive and scores for immunological infertility (1,2,22,23). These antibodies are found in approximately 6% of infertile men (13). Anti-sperm antibodies belong to different immunoglobulin classes, but only those of the IgG and the IgA class are clinically relevant (18). The former display cytolytic effects and are adequately detected on spermatozoa or in seminal plasma with the SpermMar Test IgA. Antibodies that react with C3b of the IgG class, which mainly have agglutinating properties (16), rarely occur without antibodies of the IgA class and may be more significant. Indeed, patients containing sperm antibodies often have IgG antibodies, whereas IgA antibodies alone have very little chance of interfering with their partner’s fertility through natural ways (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 antibodies are secreted by the accessory sex glands (23). They are present on the spermatozoa and sometimes in seminal plasma, but usually are absent in serum. Therefore, testing for anti-sperm antibodies of the IgA class in 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 concentration or motility, especially in 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 re- suspension in medium. These spermatozoa are mixed with the beads which are coated with antibodies anti-IgA. The formation of mixed agglutinates of motile spermatozoa with beads indicates the presence of IgA antibodies against spermatozoa in the seminal plasma (15,10,11).

**Product Order Codes**

SPMA S  SpermMar Test IgA single kit – 50 tests

SPMA C  SpermMar Test IgA complete kit – 50 tests

**Materials Included with the Test**

- 1 vial containing 0.7ml SpermMar Test IgA beads
- Microcapillary pipettes calibrated at 10 microlitres
- Rubber bulb
- Microscope slides 76x26 mm
- Vial containing 0.7ml SpermMar Test IgA beads

**MATERIALS NOT INCLUDED WITH THE TEST**

- Light microscope (with 40x to 60x magnification, bright field, dark field or phase contrast)
- Non-spermicidal condom (e.g. Male Factor Pack – Fortipro 90)

**Directions for Use**

**Specimen Collection & Preparation**

Seminal collection by masturbation is preferred. Where particular circumstances discourage collection by masturbation, specific plastic condoms are available from Fortipro for seminal collection (e.g. Male Factor Pack). Ordinary condoms should not be used for seminal collection because they may interfere with the motility and the availability of the spermatozoa. Spermatozoa 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 prevent a homogenous suspension.

**Direct SpermMar Test IgA for the Detection of Antisperm Antibodies of the IgA Class on Human Spermatozoa**

1. Allow reagents and semens to adjust to room temperature.

2. On a clean work surface:
   - 10 microlitres of semen
   - 10 microlitres of SpermMar Test IgA Latex particles
   - 1 microlitre of Albumin of US origin
   - 1 microlitre of SpermMar Test IgA

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

4. The test is performed in a 60mm petri dish and a cover glass is placed over the mixture.

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

6. Observe the proportion in a 60x chamber (e.g. a petri dish containing a统治 area of the field of view.

7. The diagnosis of immunological infertility is suspected when 10-35% of the motile spermatozoa are attached to latex particles. 4% 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 spermatozoa not covered by Latex particles. The Latex particles may, but usually do not agglutinate among themselves. In the presence of anti-sperm antibodies the spermatozoa will react with the particles and, one or later 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.

In general, the proportion of motile spermatozoa reacting in the SpermMar Test IgA is smaller than that finding in the SpermMar Test IgG, but the former 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 IgG, indicating the presence of secondary 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 SpermMar Test IgA.

**Limitations of the Method**

The direct SpermMar Test IgA can only be performed on extracellular antibodies present in the semen samples. Samples with very low sperm concentration or motility may yield false negative results.

**Performance Characteristics**

Several hundreds of semen samples have been tested with the direct mixed antiglobulin reaction and the direct SpermMar test for IgA. The results were similar in 9% of the cases. In 3% of the SpermMar Test IgA detected antibodies whereas the mixed antiglobulin reaction test used could not detect cells were negative. In such cases the proportion of spermatozoa reacting in the SpermMar test usually was less than 10%. The results of the SpermMar Test IgA were proven accurate after comparison with immunoassay can be negative.

**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°C when not in use. DO NOT FREEZE REAGENT. Suitable for transport or short term storage at elevated temperatures (up to 5 days) at 37°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.

**Bibliography**


**Technical Support**

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