SpermMar IgG Test Controls

Reference: 15518 (SpermMar IgG Positive Control)
15517 (SpermMar IgG Negative Control)

For laboratory use only; other uses must be qualified by the end user

INTENDED USE

In the Indirect SpermMar IgG Test, washed motile donor spermatozoa are incubated with diluted, decomplemented patient serum of male or female origin. If the serum contains IgG antisperm antibodies, these will cover the donor spermatozoa, which will react positively in the SpermMar IgG Test. The SpermMar IgG Positive Control contains ready-to-use patient serum with IgG antisperm antibodies levels greater than 80%. The SpermMar IgG Negative Control contains ready-to-use patient serum with IgG antisperm antibodies levels less than 20%.

REAGENT STORAGE

Store SpermMar Control reagents at 2º to 8º C when not in use. DO NOT FREEZE REAGENTS. Reagents are ready to use. Mix well before use.

MATERIALS REQUIRED (*not provided)

SpermMar IgG Anti-Sperm Antibody Test*	Volumetric pipet*	Microscope (400X or 600X magnification) *
Cover glasses *	Microscope slides *	Test Tube*

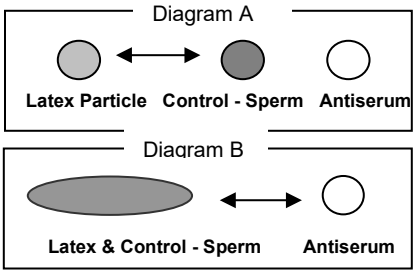
INSTRUCTIONS FOR USE

1. Allow all reagents and specimens to come to room temperature.

2. Wash the motile donor spermatozoa by approved laboratory method. Adjust the sperm concentration to 20x10^{6}spermatoza/mL with in modified HTF medium or other approved medium.

3. Mix 50µ of SpermMar Control with 50µ of the washed motile donor sperm. Incubate for 60 minutes at 37°C.

4. On a clean, dry microscope slide place:
   - 1 drop (10µ) SpermMar IgG Control - Sperm mixture
   - 1 drop (10µ) SpermMar IgG Latex Particles
   - 1 drop (10µ) SpermMar IgG Antiserum



5. Mix the Latex particle and SpermMar IgG Control - Sperm mixture (Diagram A).

6. Mix the Latex particle & Control -Sperm mixture with the Antiserum (Diagram B).

7. Place a cover glass on the mixture and observed under a light microscope using a 400x or 600x magnification (phase contrast or dark field illumination may also be used to facilitate reading of the slides).

8. Read the results after 2-3 minutes. Observe for latex particles attached to motile sperm. Count 100 spermatozoa to determine the percentage reactive sperm. If no attachment of 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).

   *Any oocyte incubation medium may be used, provided it does not contain serum or albumin.

   *To prevent evaporation during incubation, always cover with parafilm.

RESULTS

When the test is properly performed, the absence of sperm antibodies will be shown by freely moving spermatozoa uncovered 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. The SpermMar IgG positive control test should yield 80% or more of the motile spermatozoa covered with latex particles. The SpermMar IgG negative control should yield 20% or fewer spermatozoa covered with latex particles.

LIMITATIONS OF THE PROCEDURE

The indirect SpermMar-Test can only be performed if motile spermatozoa are present in the semen. Samples with poor motility may yield false negative results.

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. Although SpermMar IgG Positive and Negative controls havebeen tested for HIV and hepatitis the user should always wear protective clothing when handling the control sera.

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