

## Sperm Antibody A/G Serum Controls

### INTENDED USE

Sperm Antibody A/G Serum Controls are used as controls in sperm antibody assays such as ImmunoSpheres<sup>®</sup>, MarScreen<sup>®</sup> IgG and MarScreen<sup>®</sup> IgA.

### SUMMARY

Because of the impracticality of using specimens of antibody-positive sperm as a positive control in direct sperm antibody tests, serum controls are used instead. This kit contains:

**Sperm Antibody Positive A/G Serum:** 1 ml heat-inactivated human serum containing antibodies of the IgA and IgG classes that bind to human sperm, with 0.1% sodium azide.

**Sperm Antibody Negative Serum:** 1 ml heat-inactivated human serum containing no antibodies that bind to human sperm, with 0.1% sodium azide.

### PRECAUTIONS

The Sperm Antibody Positive A/G Serum and the Sperm Antibody Negative Serum have been tested and found negative for HIV antibody and hepatitis B surface antigen, but negative results do not guarantee absence of virus. Handle all specimens as capable of transmitting HIV or hepatitis. Specimens should be disposed of in accordance with OSHA guidelines. Product should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully.

### STABILITY AND STORAGE

The reagents are stable to the stated expiration date when stored at the required temperature. Store reagents at 2–8°C. Do not freeze.

### USER QUALITY CONTROL

These serum controls may look cloudy due to lipemia. Lipemic serum will not interfere with test results. Always use positive and negative controls.

### SPECIMEN COLLECTION AND PREPARATION

Semen should be collected in a clean collection cup. The semen sample can be stored at room temperature until the time of use.

### PROCEDURE

**Materials Provided with Sperm Antibody A/G Serum Controls (#006050):** Sperm Antibody Positive A/G Serum, Sperm Antibody Negative Serum.

**Materials Not Provided:** Indirect sperm antibody assays.

#### Preparation of Antibody Positive Sperm

1. Start with sperm known to be negative for antibodies.
2. Wash sperm free of seminal plasma.
3. Incubate the washed sperm with Sperm Antibody Positive A/G Serum at a final dilution of 1:10
4. Wash the sperm free of Sperm Antibody Positive A/G Serum and then use the prepared sperm as a positive control for antibody-positive sperm.

#### Preparation of Antibody Negative Sperm

1. Start with sperm known to be negative for antibodies.
2. Wash sperm free of seminal plasma.
3. Incubate the washed sperm with Sperm Antibody Negative Serum at a final dilution of 1:10
4. Wash the sperm free of Sperm Antibody Negative Serum and then use the prepared sperm as a negative control for antibody-negative sperm.

The researcher should determine the optimal working dilutions of these products. The following information is provided as a guideline to the researcher:

**Indirect sperm antibody assays (in serum):** Follow the manufacturer's directions for testing serum.

**MarScreen<sup>®</sup>:** Dilute serum 1:16 before using in the Indirect MarScreen IgG or the Indirect MarScreen IgA test. For example, add 20 µl serum to 300 µl sperm washing medium.

**ImmunoSpheres<sup>®</sup>:** Use the serum at a final dilution of 1: 10 in either indirect Anti IgG or indirect Anti IgA test. For example, add 50 µl serum to 400 µl sperm washing medium and 50 µl washed sperm (~50 million motile sperm/ml) suspension.

The researcher should establish the % total binding of the **Sperm Antibody Positive A/G Serum** when it is used in either indirect Anti-IgA test.

### EXPECTED RESULTS

**Sperm Antibody Positive A/G Serum** should produce a positive reaction for IgA and IgG sperm antibody assays.

**Sperm Antibody Negative Serum** should produce a negative reaction for sperm antibody assays.

### LIMITATIONS OF PROCEDURES

User should determine optimal working dilutions for the relevant assay.

### CONTACT

CalibreScientific US, Inc. offers a complete line of reagents, stains, and QC1™ Quality Control Slides for AFB, Parasitology, Bacteriology, and Mycology processing. CalibreScientific US, Inc. also provides O&P collection systems and concentration devices for Parasitology, as well as products for the evaluation of male fertility. For Technical Assistance, email [Technical@AlphaTecSystems.com](mailto:Technical@AlphaTecSystems.com), and for Customer Service, email [Sales@AlphaTecSystems.com](mailto:Sales@AlphaTecSystems.com), or call either [+1] 800.221.6058 (USA) or [+1] 360.260.2779 between 8AM and 4PM Monday through Friday, Pacific Time.

### WARRANTY

This product is warranted by CalibreScientific US, Inc. to perform as described in the labeling and literature supplied. CalibreScientific US, Inc. disclaims any implied warranty or merchantability or fitness for any other purpose, and in no event shall CalibreScientific US, Inc. be liable for any consequential damages arising out of aforesaid express warranty.

### TRADEMARKS:

MarScreen<sup>®</sup> and ImmunoSpheres<sup>®</sup> are trademarks of CalibreScientific AMER IP LLC., 6201 Trust Dr, Holland, OH 43528.

### PRODUCT CODES:








0006050 Sperm Antibody A/G Serum Controls, 2 x 1 ml

## Sperm Antibody A/G Serum Controls



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### GLOSSARY OF SYMBOLS

- LOT** Batch code / Numéro de lot / Número de Lote / Numero di lotto / Lot Nummer / Lotnummer / Lotnummer / Šaržna številka / Número de lote
- REF** Catalog number / Référence du catalogue / Número de catálogo / Numero di catalogo / Katalognummer / Catalog nummer / Het aantal van de catalogus / Kataloška številka / Número de catálogo
- IVD** In vitro diagnostic medical device / Pour usage diagnostique in vitro / Para uso diagnóstico in vitro solamente / Solo per uso diagnostico in vitro / Nur zur Verwendung als in vitro-Diagnostikum / Alleen voor in vitro diagnostisch gebruik / För invitrodiagnostik enbart / Samo za invitro diagnostiko / Apenas para uso em diagnóstico in vitro
-  Use-by date / Utiliser avant la date de péremption indiquée / Use antes de la fecha indicada / Utilizzare entro la data indicata / Bis zum angegebenen datum verbrauchen / Gebruik door vermelde datum / Använd innan angivet datum / Porabiti do navadenega datuma / Usar até à data indicada
-  Manufacturer / Fabricant / Fabricante / Produttore / Hersteller / Fabrikant / Fabrikant / Proizvajalec / Fabricante
-  Caution / Attention / Cuidado / Attenzione / Achtung / Voorzichtig / Iaktag försiktighet / Previdno / Atenção
-  Temperature limit / Conserver aux températures indiquées / Almacene entre las temperaturas indicadas / Conservare a temperature comprese fra quelle indicate / Im angegebenen temperaturbereich aufbewahren / Opslaan bij een temperatuur tussen / Förvara mellan angivna temperaturer / Shranjevati med navedenimi temperaturami / Armazene entre as temperaturas indicadas
-  Contains sufficient for <n> tests / Contenu suffisant pour <n> tests / Contiene suficiente para <n> pruebas / Contenuto sufficiente per <n> tests / Enthält ausreichend für <n> untersuchungen / Inhoud voldoende voor <n> testen / Innehåller tillräckligt för <n> tester / Vsebina zadostuje za <n> testov / Contém quantidade suficiente para <n> testes
-  Consult instructions for use / Consulter la notice d'utilisation / Consulte las instrucciones para el uso / Consultare le istruzioni per l'uso / Bitte beachten Sie die Anwendungsvorschriften / Raadpleeg instructies voor gebruik / Konsultera bruksanvisningen innan användning / Glej navodila za uporabo / Consulte instruções para o uso
-  Do not reuse / Ne pas réutiliser / No reutilizar / Non riutilizzare / Nicht wiederverwenden / Niet hergebruiken / Återanvänd inte / Ne uporabljajte znova / Não reutilize