DRG® Ovary Ab Latex Hemagglutination (RAP-4938)

As of 25 Feb. 2009 (Vers. 1.0) **USA: RUO**

INTENDED USE

The Ovary Antibody Latex Agglutination Test is a quick, reliable, semi quantitative test for the detection of antibodies directed against human ovary antigens. This test may be used with serum.

CLINICAL RELEVANCE

Antibodies directed against ovary antigens in serum can cause infertility in women. The application of the Ovary Antibody Latex Agglutination Test is recommended for monitoring disorders of fertility and premature ovarian failure.

FIELDS OF APPLICATION

The Ovary Antibody Latex Agglutination Test can be applied in the clinical practice for the confirmation or the exclusion of antibodies against ovarial tissues as the cause of fertility problems.

PRINCIPLES OF THE ASSAY METHOD

In the case of presence of specific antibodies directed against ovary antigens in the sample, latex particles coated with antigen will agglutinate within 1 - 2 minutes.

REAGENTS

(sufficient for 50 determinations)

1.	Ovary **antigen suspension** (white screw cap)	0.55 ml
2.	**Positive control** (green screw cap)	0.3 ml
3.	**Negative control** (red screw cap)	0.3 ml
4.	**Dilution buffer**, concentrated 3x (mix before use with 60 ml distilled water)	30 ml
5.	**Stirrer sticks**	10 x
6.	**Slides**	5 x

MATERIALS REQUIRED BUT NOT INCLUDED

1. Tubes for the dilution of the samples.
2. Distilled or deionised water.
3. Microliter pipettes with disposable tips: 10 µl, 20 µl and 500 µl.
4. Please use only calibrated pipettes.

As of 25 Feb. 2009 (Vers. 1.0) **USA: RUO**

WARNINGS AND PRECAUTIONS

1. This kit is intended for in vitro use only.
2. Do not pipette reagents by mouth.
3. Please regard all samples as potentially infectious and handle them with utmost care.
4. Handling and disposal should be in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation where this exists.

INSTRUCTIONS FOR REAGENT PREPARATION

1. The components of this kit are intended for use as an integral unit and should not be interchanged with the components of other kits.
2. All reagents and specimens must be brought to room temperature before use.
3. All reagents have to be mixed without foaming.
4. Once the test procedure has been started, all steps should be carried out without interruption.
5. Use new disposable tips for each specimen.

STORAGE INSTRUCTIONS AND SHELF LIFE INFORMATION

1. Store the reagents at 2 °C – 8 °C (36 °F – 46 °F).
2. The reagents remain stable until the expiration date of the kit.
3. Put caps back on the vials immediately after use.

SAMPLE MATERIAL

Serum

SPECIMEN COLLECTION AND PREPARATION

Collect blood by venipuncture, allow to clot, and separate serum by centrifugation at room temperature; avoid haemolysis. Avoid repeated freezing and thawing. Store tubes closed as they may be a danger of contamination or alteration of concentration.

1. Handle all samples with utmost care since they may be infectious.
2. There are no known interferences with extrinsic factors or other substances.
3. Samples may be stored at different temperatures for the following time-spans:
   - Environmental temperature up to 30 °C (86 °F): up to three days
   - Refrigerator temperature (2 – 8 °C / 36 °F – 46 °F): up to one week
   - Household freezer temperature (-10 °C – -20 °C / 14 °F – -4 °F): up to one year

DRG® Ovary Ab Latex Hemagglutination (RAP-4938)

As of 25 Feb. 2009 (Vers. 1.0) **USA: RUO**

ATTENTION! There are no test methods available which may guarantee that Hepatitis B virus, Human Immunodeficiency Virus (HIV/HTLV-III/LAV), or other infectious agents are absent from the reagents in this kit. Therefore, all human blood products, including patient samples, should be considered potentially infectious.

ASSAY PROCEDURE

1. Preparation of dilution buffer:
   Dilute the concentrated dilution buffer (30 ml) with 60 ml distilled water.
2. Dilute specimen 1:400
   (for example: first step 10 µl of serum + 90 µl of dilution buffer, yielding a dilution of 1:10,
   then second step: 10 µl of the first dilution + 390 µl dilution buffer, yielding a dilution of 1:40 and therefore an end dilution of 1:400).
3. Make a serial dilution using log 2: 1:800, 1:1600, 1:3200
4. Positive and negative controls have to be used undiluted.
5. **Vigorously mix the antigen suspension before use, for example by using a Vortex mixer for at least 1 minute.**
6. Dispense 10 µl of antigen suspension into marked sector (circular shape) on the slide.
   Add 20 µl of controls and diluted specimen (1:400, 1:800, 1:1600, 1:3200).
7. Intensively mix antigen suspension and samples on the slide using a stirrer stick provided.
8. Move slide slowly by hand.
9. Inspect the slide visually for agglutination after 2 min.

Please note that an agglutination is considered to be positive with regard to the presence of anti-ovary antibodies only in specimen dilutions of 1:400 and higher. Therefore in case of agglutination please carry on with titration until no more agglutination appears.

EVALUATION OF THE RESULTS

1. Positive reaction:
   After 2 minutes a definite agglutination characterised by a more or less coarse granulation indicates a positive result. For serum a positive response in the 1:400 dilution is equivalent to 10 IU/ml in the DRG Anti-Ovary Antibody ELISA (order code EIA-2937).
2. Negative reaction:
   A result is considered negative if no definite agglutination is discernible. In this case the reaction mixture remains liquid with a milky appearance.

Attention: Please don't wait longer than 3 minutes after start of the agglutination reaction, otherwise the results may become unclear, because of evaporation effects.

LIMITATIONS OF THE ASSAY

- At temperatures higher than 30 °C (86 °F) the samples should be transported cooled or refrigerated.

DRG International Inc., USA

Fax: (908) 233-0758 • E-mail: corp@drg-international.com • **Web:** www.drg-international.com

- Severely haemolytic or lipaemic sera or sera from patients with liver diseases should not be used. Results may be adversely affected by certain pathologic conditions, such as poly- and monoclonal gammapathies, autoimmune diseases or by an altered immune status.

DRG® Ovary Ab Latex Hemagglutination (RAP-4938)

As of 25 Feb. 2009 (Vers. 1.0) **USA: RUO**

SYMBOLS USED WITH DRG ASSAYS

Symbol	English	Deutsch	Français	Español	Italiano
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
LOT	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributore
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità

Symbol	Portugues	Dansk	Svenska	Ελληνικά
	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisningen	Εγχειρίδιο χρήστη
CE	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
IVD	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
REF	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
LOT	No do lote	Lot nummer	Batch-nummer	Αριθμός Παρτίδος
		Indeholder tilstrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura de conservação	Opbevarings-temperatur	Förvaringstempratur	Θερμοκρασία αποθήκευσης
	Prazo de validade	Udløbsdato	Bäst före datum	Ημερομηνία λήξης
	Fabricante	Producent	Tillverkare	Κατασκευαστής
Distributed by				
Content	Conteúdo	Indhold	Innehåll	Περιεχόμενο
Volume/No.	Volume/Número	Volumen/antal	Volym/antal	Όγκος/αριθ..