DRG® Ovary Ab Hemagglutination (RAP-4939)

CE

Revised 1 Mar. 2011 rm (Vers. 2.1) **USA: RUO**

Please use only the valid version of the package insert provided with the kit.

This kit is intended for Research Use Only.

Not for use in diagnostic procedures.

INTENDED USE

With the Ovary Antibody Haemagglutination Test the titer of ovary antibodies is detected in human serum.

PRINCIPLES OF THE ASSAY METHOD

The test is based on the haemagglutination test principle using sensitised red blood cells (sSRBC) of sheep as target antigen. Antibodies in the samples agglutinate with sSRBC within 90 minutes.

REAGENTS

(sufficient for 40 determinations)

1.	**Antigen suspension** (sSRBC)	0.45 ml
2.	**Positive control**	0.30 ml
3.	**Negative control**	0.20 ml
4.	**Dilution buffer** (ready for use)	20 ml
5.	**Microplate**	1 x

MATERIALS REQUIRED BUT NOT INCLUDED

1. Tubes for the dilution of the samples.
2. Microtiter pipettes with disposable tips: 10 µl, 20 µl and 50 µl.
3. Please use only calibrated pipettes.

WARNINGS AND PRECAUTIONS

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

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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 continued without interruption.
5. Pipette all reagents and samples onto the bottom of the wells. Use new disposable tips for each specimen.
6. Before starting the assay, all reagents to be used should be prepared and ready for immediate use. This will ensure equal time periods for each pipetting step without interruption.
7. It is recommended to effect all tests in double determination in order to minimize the consequences of pipetting or handling errors.
8. The optimum laboratory room temperature is 19 °C (66 °F)..

STORAGE INSTRUCTIONS AND SHELF LIFE INFORMATION

1. Store the reagents at 2 – 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 International Inc., USA

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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 samples, should be considered potentially infectious.

ASSAY PROCEDURE

1. Inactivate the serum for 30 min at 56 °C.
2. Prepare a serial dilution of positive control with dilution buffer using log 2 (1:4, 1:8, 1:16, 1:32).
3. Use the negative control undiluted.
4. Dilute serum initially 1:4 (100 µl of specimen + 300 µl of dilution buffer).
5. Dispense 50 µl of the diluted specimen, negative control and serial dilution of positive control (1:4, 1:8, 1:16, 1:32) into each well.
6. Add 10 µl of antigen suspension (sSRBC) to each well.
7. Mix by tapping gently the plate with your fingertips.
8. Incubate microplate 90 min at room temperature without movement.
9. Inspect the wells visually for agglutination after 90 min. In case of a positive reaction the serum should be serially diluted in order to establish the titer of antibodies.

LIMITATIONS OF THE ASSAY

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

Version 2011-02-21~rm

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