INTRODUCCIÓN
Toxoplasmosis is an infectious disease caused by a protozoan called Toxoplasma Gondii, which affects both humans and animals. It is a frequent infection, usually benign and asymptomatic and of special importance in pregnant women as this parasite can cross the placenta and affect the fetus. Acute infection during the first trimester of gestation poses the greatest risks of fetal lesions, which range from miscarriage to severe visceral and neurological damages.

PROPOSED USE
For determining the presence of anti-toxoplasma antibodies in human serum

MATERIALS
Micropipettes

FUNDAMENT OF THE METHOD
The test is based on the principle of agglutination on a glass slide. The reagent contains polystyrene latex particles sensitized with Toxoplasma Gondii antigens in soluble form. Agglutination is visible at a concentration of anti-toxoplasma antibodies in the sample equal to or higher than 4 IU/ml.

CONTENT

R1 Latex Toxo
Latex TOXOPLASMA -suspension
White cap
Phosphate Tampon solution 20 mmol/L
Sodium azide 0.1 %

R2 Positive Control
Red Cap
Positive Control: Rabbit serum.
Anti-toxoplasma antibodies concentration over 30 IU/ml
Sodium azide 0.1 %
Glycine tampon solution 150 mmol/L
R3 Negative Control

Blue Cap

Negative Control: Rabbit serum
Anti-toxoplasma antibody concentration 0 IU/ml

Glycine Tampon solution 150 mmol/L
Sodium Azide 0.1 %

Slides for latex
Code: 1200202: 16 x 6 glass slides

Applicators
Code: 1200202: 2 packs x 25

CALIBRATION
The sensitivity of the reagent has been adjusted against the 3er WHO anti-toxoplasma International standard.

PREPARATION AND STABILITY
The R1 Latex reagent is a suspension of latex particles which should be homogenized by shaking gently before using. Use a pipette to dispense exactly 25 μl of latex which is the ideal volume for a good sensitivity. Store reagents at 2-8 °C. Do not freeze. Under these conditions the components will maintain their reactivity until the date of expiry indicated on the label.

SAMPLE
Serum, when preserved at 2 - 8 °C, will maintain its activity for 2 days. Inactivation not required.
Do not use hemolyzed or highly lipemic serum as this can cause non-specific agglutination.

PROCEDURE
Qualitative method
1. Allow reagents and controls to stand at room temperature.
2. Homogenize the R1 Latex reagent by shaking gently.
3. Use the Positive and negative Controls to monitor the reactivity of the reagent (see procedure below).
4. Use a pipette to dispense 50 μl of the trial serum onto the circle on the glass slide. DO NOT DILUTE.
5. Use a pipette to dispense 25 μl of R1 Latex next to the serum.
6. Mix with an applicator and spread the mixture throughout the circle. Place the slide on the rotatory stirrer (80-100 RPM) or gently rotate in circular movements. Note the appearance or absence of agglutination after 4 minutes. Allowing the reaction to continue
may give false results.

**INTERPRETATION**
Examine macroscopically for the presence or absence of agglutination immediately after withdrawing the glass slide from the stirrer. The presence of agglutination indicates an anti-Toxo antibody concentration equal to or over 4 IU/ml.

**Semi-Quantitative Method**
1. Prepare two dilutions of the sample in a saline solution 9 g/L. Proceed with each dilution as indicated in the qualitative test.
2. In the semi-quantitative method, the titer is defined as the highest dilution with positive results.

**CALCULATION**
The approximate anti-Toxo antibody concentration in the sample of the patient is obtained by means of the following formula: $4 \times \text{Antibody Titer} = \text{IU/ml}$

**QUALITY CONTROL**
Use the positive and negative controls for monitoring the reactivity of the reagent and as a comparison model for interpreting results.

**REFERENCE VALUES**
Up to 4 IU/ml.
Each laboratory should establish its own reference values.

**CHARACTERISTICS OF THE METHOD**
1. Detection threshold: 4 (3-7) IU/ml, under the conditions described in the assay.
2. Prozone value: Not observed until a value of 200 IU/ml is reached. If negative results are obtained with a sample suspicious of being positive, since it was obtained from a patient with toxoplasmosis, the test should be repeated at a dilution of 1/5 of the serum in a NaCl solution 9 g/L.
3. Sensitivity of the diagnosis: 95 %.
4. Specificity of the diagnosis: 90 %.

**INTERFERENCES**
Bilirubin (20 mg/dl), hemoglobin (10 g/L), lipids (10 g/L) and rheumatoid factors (300 IU/ml) do not interfere.

**LIMITATIONS OF THE METHOD**
Patients with liver cell disease can give false positive results. Approximately 25 % of the sera contain heterophil antibodies which may give false positive results.

The clinical diagnostic should not be based only on the results of one assay. Consideration should also be given to the clinical record of the patient.

**PRECAUTIONS**
Contains small amounts of sodium azide. Avoid contact with irritated skin and mucosa.

REFERENCE

PRESENTATION

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