CRP SLIDE

Latex agglutination

REF. 7703 100 tests with controls and accessories
REF. 7704 100 tests without controls and accessories
REF. 7788 50 tests with controls and accessories
REF. 7789 300 tests without controls and accessories

CE IVD

DNV CERTIFIED COMPANY
UNI EN ISO 9001:2008
UN EN ISO 13485:2012

GIESSE DIAGNOSTICS

INTENDED USE

Qualitative determination of C - Reactive Protein (CRP)

PRINCIPLE

CRP SLIDE is a slide agglutination test for the qualitative and semi-quantitative detection of C - Reative Protein (CRP) in human serum.

Latex particles coated with goat IgG anti-human are agglutinated when mixed with samples containing CRP.

SAMPLE

Fresh Serum. Stable 7 days at 2-8°C or 3 months at -20°C.

Samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolized or lipemic samples.

KIT COMPONENTS

Reagent (A) CRP Latex Volume = 2.5/5.0 ml	Latex particles coated with goat IgG anti-human CRP, pH 8.2, Sodium azide 0.95 g/l
Control (+) CRP Volume = 0.5 ml	Human serum with a CRP concentration > 20 mg/l Sodium azide 0.95 g/l
Control (-) CRP Volume = 0.5 ml	Animal Serum Sodium azide 0.95 g/l
Stirrers	1 o 2 pz
Reaction Slide	1 o 2 pz

The Reagents are stable until the expiration date printed on the label, when stored tightly closed at 2-8°C. Once opened, the reagents are stable one month at 2-8°C if contamination is avoided. Do not freeze.

Keep bottles closed when not in use.

REAGENT PREPARATION

All the kit components are ready to use.

PRECAUTIONS AND WARNINGS

Biological risk for Control (+)

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Use the normal precautions required in the laboratory.

Components from human origin have been tested and found to be negative for the presence of HbsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

Dispose of waste according to local laws.

PROCEDURE

Qualitative Method:

Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Gently mix the latex.

Dispense 50 µl of serum upon a selected spot of the reaction slide, add one drop of latex and accurately mix with a stirrer paying attention to uniformly distribute the liquid on the selected spot. Rotate the slide and observe within 2 minutes possible agglutination. False positive results could appear if test is read later than 2 minutes.

Semi-quantitative method:

Make serial two fold dilutions of the sample in saline solution.

Proceed for each dilution as in the quantitative method.

READING AND INTERPRETATION

Examine the presence or absence of visible agglutination.

The presence of agglutination indicates an CRP concentration equal or greater than 6 mg/l.

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate CRP concentration in the sample is calculated as follow:

6 x CRP Titer = mg/l

EXPECTED VALUES

Up to: 6 mg/l

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

Positive and Negative Controls are recommended to monitor the performance of the reagent and to have a better results interpretation.

PERFORMANCE

Sensitivity: 6 (5-10) mg/l

Prozone effect: No prozone effect up to 1600 mg/l.

Diagnostic sensitivity: 95.6 %

Diagnostic specificity: 96.2 %

Interferences: bilirubin does not interfere up to 20 mg/dl. Lipemia and hemoglobin do not interfere up to 10 g/l. Rheumatoid factors (100 U/ml) interferere.

METHOD LIMITATIONS

False positive Results may be obtained in case of: Rheumatoid factor > 100 U/ml; bacterial contamination in the sample andthe controls; traces of detergent such as slide washing residuals.

False negative Results can be obtained with samples strongly positive (prozone effect). In this case, repeat the test using 20 µl of the sample.

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES

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