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IVD AND MEDICAL DEVICES
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C - REACTIVE PROTEIN (CRP)

QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION
LATEX AGGLUTINATION

IVD CE

Packaging
REF. N° ND202 (with Controls, Slides and Stirrers) 100 Test
REF. N° ND222 (Latex only) 100 Test

Reaction principle

When a serum containing C - Reactive Protein is mixed with the reagent that contains latex particles coated with anti - CRP antobody an agglutination appears.

Reagents Composition, Contents and Safety warnings

1. Latex Suspension (1x5 ml)
Latex particles coated with anti - CRP Antibody
Sodium Azide 0.095 %

2. Positive Control * only in REF N° ND202 (1x0,5 ml)
Stabilized solution containing human CRP with a concentration between 30 - 50 mg/l
Sodium Azide 0.095 %

3. Negative Control only in REF N° ND202 (1x0,5 ml)
Proteic solution non reactive with the latex
Sodium Azide 0.095 %

4. Reaction Slides only in REF N° ND202 (8)

5. Plastic Stirrers only in REF N° ND202 (50)

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).
Further information on the risks to health and / or the environment are given in the data sheet.

Storage and Stability of Reagents

Store the kit at 2 - 8° C

All the components are stable until the stated expiration date if stored closed and refrigerated

Preparation and Stability of working solution

Latex Suspension: **liquid and ready to use**
Positive and Negative Control: liquid and ready to use

Gently mix the Latex to obtain a homogeneous suspension before use.

Bring reagents at Room Temperature before use

Samples

Fresh serum

Serum may be stored at 2 - 8°C for 7 days, for longer storage should be at - 20° C

Precaution

BIOLOGICAL RISK

* Each unit of source material used in the preparation of Positive Control has been tested by a licensed method and found no reactive for HbsAg and negative for Antibodies to HCV and HIV1/2.
However no known test can offer complete assurance that Products derived from human blood will not transmit Hepatitis,
AIDS or other infectious diseases. This products, like all materials of human origin, should be handled as potentially infectious biological material

Safety Precautions

For in vitro diagnostic use only
Do not pipette by mouth
Exercise the nornal precautions required for handling laboratory reagents

Procedure

Qualitative

Reagents	1ª reactive area Sample	2ª reactive area Positive Control	3ª reactive area Negative Control
Sample	1 drop (~50 µl)		
Positive Control		1 drop (~50 µl)	
Negative Control			1 drop (~50 µl)
Latex	1 drop (~50 µl)	1 drop (~50 µl)	1 drop (~50 µl)

Mix and spread with the stirrers to fill the area. Rotate the slide (also with a mixer at 100 rpm) for 2 minutes and observe for any agglutination which should occur

Results

Every visibile agglutination within 2 minutes indicates positive result
Absence of agglutination indicates negative result

Positive samples should be titrated **(see semiquantitative procedure)**

Semiquantitative

Pipette in the reactive areas:

Reagents	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6
Saline Solution	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
Sample	50 µl	50 µl from area 1	50 µl from area 2	50 µl from area 3	50 µl from area 4	50 µl from area5
discard 50 µl from the last area						
Latex	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
Titre (mg/l)	12	24	48	96	192	384

Results interpretation

Generally in the healthy grown - up peoples has a titre ≤ 5 mg/l.
In case of disease, after 4/8 hours from acute state, the concentration can arrive up to 500 mg/l
The mean value of C - Reactive rotein found in 143 samples from healthy adults was 0.64 mg/l and the range between 0.08 and 3.11mg/l (Clinical Chemistry 43:1, 52 - 58 1997)

Each laboratory should establish its Normal Reference Range

Performance Characteristics

A. DETECTION LIMIT:
6 mg/l (5 - 10 mg/l)

B. PROZONE EFFECT:
No prozone effect was detected up to 1634 mg/l of CRP concentration

C. ACCURACY
Comparation between this method and another commercial one on 125 samples, gave the following results:

		FUTURA SYSTEM +	FUTURA SYSTEM -	TOTAL
ANOTHER METHOD	+	44	2	46
	-	3	76	79
TOTAL		47	78	125

D. INTERFERENCES
1. Haemoglobin till to ≤1000 mg/dl does not interfere
2. Bilirubin till to ≤ 20 mg/dl does not interfere
3. Lipids till to ≤1000 mg/dl do not interfere
4. RF concentration higher than 100 IU/ml could interfere

Notes

1. Do not read beyond 2 minutes, false agglutinations may occur
2. The final diagnosis should not be made using a single test but should be based on more than one result and confirmed by clinical data
3. Lipaemic or turbid sera should give false positive results

Quality control

To distinguish a possible agglutination of suspension one's own it is necessary to be run with each serie of tests the controls, Positive and Negative, supplied with the kit

Bibliography

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