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IVD AND MEDICAL DEVICES
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ANTI-STREPTOLYSIN O (ASO)

QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION
Latex Agglutination

IVD CE

Packaging
REF. N° ND101 (with Controls, Slides and Stirrers) 100 Tests
REF. N° ND111 (Latex only) 100 Tests

Reaction principle
When a serum containing Streptolysin O Antibody (≥ 200 IU/ml) is mixed with the reagent that contains latex particles coated with O - Streptolysin, an agglutination appears

Reagents composition, Contents and Safety warnings

1. Latex Suspension (1x5 ml)
Latex particles coated with Streptolysin O
Preservatives and stabilizers

2. Positive Control * only in REF. N° ND101 (1x0,5 ml)
Stabilized solution containing enough human ASO titre to give a visible agglutination

3. Negative Control only in REF. N° ND101 (1x0,5 ml)
Proteic solution non reactive with the latex

4. Reaction Slides only in REF. N° ND101 (8)

5. Plastic Stirrers only in REF. N° ND101 (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 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.

Keep 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 be at - 20° C.

Biological risk

Each unit of source material used in the preparation of Positive Control has been tested by a licensed method and found non 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. These products, like all material 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
Saline Solution	50 µl	50 µl	50 µl	50 µl	50 µl
Sample	50 µl	25 µl	50 µl from area1	50 µl from area 2	50 µl from area 3
discard 50 µl from the last area					
Latex	50 µl	50 µl	50 µl	50 µl	50 µl
Title (IU/ml)	400	600	800	1200	1600

Results interpretation
95% of the healthy grown - up people has a titre ≤ 200 IU/ml.
A titre > 250 IU/ml tally in the schoolmen.
Even if the titre results very high, the final diagnosis should not be made using a single determination but should be based on more than one result
(Repeat the test every 15 days for 4 - 6 weeks)
High ASO titre indicates an ordinary Streptococcal Infection or acute rheumapyra.
In different conditions the titre is very hight and persist for a long time

Performance Characteristics

A. DETECTION LIMIT:
200 IU/ml

B. PROZONE EFFECT:
No prozone effect was detected up to 1500 IU/ml of ASO concentration

C. ACCURACY:
Comparison between this method and another commercial, on 118 samples, gave the following results:

		FUTURA SYSTEM +	FUTURA SYSTEM -	TOTAL
ANOTHER METHOD	+	48	1	49
	-	2	67	69
TOTAL		50	68	118

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 till to ≤ 300 IU/ml does not 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 Negatice, supplied with the kit

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