



## Declaration of Conformity

for Latex and slide agglutination kits

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009.

In accordance with Article 9(1) and by reference to Annex III, Rapid Labs Ltd has assessed the conformity for the following listed devices to the essential requirements of Directive 98/79/EC of the European Parliament and of the Council of the European Union on *in vitro* diagnostic medical devices.

<b>General Product Name:</b>	Latex and slide agglutination kits
<b>Manufacturer:</b>	Rapid Labs Ltd. Unit 2 & 2a Hall Farm, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom
<b>Variants:</b>	n/a
<b>Intended Use:</b>	The Rapid Labs Latex agglutination are tests consisting of antigen/antibody coated latex particles for the detection of infectious, physiological or auto immune conditions.
<b>Intended User:</b>	Professional use
<b>IVD Directive Category:</b>	General
<b>Notified Body:</b>	n/a
<b>CE Certificate Reference:</b>	n/a
<b>IVD Directive Assessment Route:</b>	Annex III
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Floor, Tower Street, Swatar BKR 4013 Malta

Name Rowland King

Position Managing Director

  
Signed \_\_\_\_\_

Date 04/02/2022

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.



### Appendix I – Applicable Standards

This present declaration is also in conformity with the following European and International standards:

Standard/Document Name	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN 13612:2002	Performance evaluation of in-vitro medical devices
EN 13641:2002	Elimination or reduction of risk infection related to in-vitro diagnostics
EN ISO 15223-1:2016	Medical devices - Symbols
EN ISO 23640:2015	Evaluation of stability

### Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
RL-ASO100 RL-ASO50	ASO Latex Test Kit with accessories	63271
RL-ASO100NA RL-ASO50NA	ASO Latex Test Kit w. No Accessories	63271
RL-CRP100 RL-CRP50	CRP Latex Test Kit with accessories	63234
RL-CRP100NA RL-CRP50NA	CRP Latex Test Kit w. No Accessories	63234
RL-RA100 RL-RA50	RA (RF) Latex Test Kit with accessories	55112
RL-RA100NA RL-RA50NA	RA (RF) Latex Test Kit w. No Accessories	55112
RL-LE100 RL-LE50	Systemic Lupus Erythematosus Latex test kit	54853
RL-MONO50	Mononucleosis Latex Kit	49688
RL-STA50 RL-STA100	Staphylococcus Latex Kit	51659
RL-RB100	Rose Bengal Agglutination Kit	50601
RL-WR100	Waler Rose Haemmagglutination Kit	55112

### Version History

Version	Compiled by	Date	Description
2.0	Emily Swager	04/02/2022	Update to director



# Certificate of Registration

This certificate has been awarded to

## Rapid Labs Limited

Unit 2 & 2A Hall Farm, Business Centre, Church Road, Little Bentley, Colchester, Essex, CO7 8SD, United Kingdom

in recognition of the organization's Quality Management System which complies with

**ISO 13485:2016**

The scope of activities covered by this certificate is defined below

**Please refer to the Appendix**

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
16 October 2024	10	15 October 2027	5
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
11 July 2024	0	09 November 2012	n/a

For detailed explanation for the data fields above, refer to <http://www.urs-holdings.com/logos-and-regulations>

Issued by

Mukesh Singhal - On behalf of the Schemes Manager





# Appendix to Certificate

**Design, Development, Manufacture and Supply of In-Vitro Diagnostic Products for the Blood Grouping products, Detection of Hormones, Drug of Abuse, Infectious Disease, Tumour Markers and Cardiac Markers, and the related POCT Analyzer. Supply of Glass Vials and Bottles**

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/8/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
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Issued by

Mukesh Singhal - On behalf of the Schemes Manager



# ASO Latex Kit Assay

## Anti-Streptolysin O



### CATALOGUE NUMBERS

RL-ASO50      RL-ASO50NA  
RL-ASO100    RL-ASO100NA

### INTENDED USE

The ASO-latex is a slide agglutination test for the qualitative and semiquantitative detection of anti-streptolysin O (ASO) in human serum. Latex particles coated with streptolysin O (SLO) are agglutinated when mixed with samples containing ASO.

### SUMMARY

Streptolysin O is a toxic immunogenic exoenzyme produced by - hemolytic Streptococci of groups A, C and G. Measuring the ASO antibodies are useful for the diagnostic of rheumatoid fever, acute glomerulonephritis and streptococcal infections. Rheumatic fever is an inflammatory disease affecting connective tissue from several parts of human body as (skin, heart, joints, etc...) and acute glomerulonephritis is a renal infection that affects mainly to renal glomerulus.

### MATERIALS

#### Materials provided

Latex	Polystyrene Latex particles coated with Streptolysin O. Sodium Azide: 0.9%
Control + (red cap)	Human Serum based, ASO concentration >250 IU/ML
Control - (green cap)	Human/Animal serum based, ASO negative control Sodium azide <1%

#### Following materials are available with RL-ASO50 & RL-ASO100

RL-ASO50	RL-ASO100
• 5 slide cards	• 10 slide cards
• 50 plastic stirrers	• 100 plastic stirrers
<b>Materials required but not provided</b>	
• Mechanical rotor (100 r.p.m)	• Isotonic saline
• Micropipette and tips (50µl)	

### PRECAUTIONS

- 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.
- Reagents must be stored between 2-8°C
- Do not freeze
- Store vials upright
- Reagents are provided ready to use.
- Ensure that the reagents are mixed thoroughly before use
- If reagents have particulate matter and aggregates, discard vial and contact Rapid Biotec

### SAMPLE COLLECTION AND PREPARATION

- Use fresh serum
- Serum used must not be haemolysed or contaminated or lipemic as it may affect test results.
- Storage and usage after time serum must be stored at 2-8°C.
- Use serum within 7 days

- For longer storage store at -20°C for 3 months.
- Samples with fibrin should be centrifuged

### CALIBRATION AND TRACEABILITY

Rapid Biotec ASO Visual Latex has been calibrated against NIBSC 64/002.

### LIMITATIONS

- False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsillitis, several streptococcal infections and healthy carriers.
- Early infections and children from 6 months to 5 years may cause false negative results.
- A single ASO determination does not produce much information about the actual state of the disease. Titrations at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

### DIRECTIONS FOR USE

#### Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

#### Semi-quantitative method

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

### INTERPRETATION OF RESULTS

- Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.
- The presence of agglutination indicates an ASO concentration equal or greater than 200 IU/mL.
- The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.
- The approximate ASO concentration in the patient sample is calculated as follows:  
$$200 \times \text{ASO Titer} = \text{IU/mL}$$

### QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

# ASO Latex Kit Assay

## Anti-Streptolysin O



### EXPECTED VALUES

Up to 200 IU/mL(adults) and 100 IU/mL (children < 5 years old). Each laboratory should establish its own reference range.

### PERFORMANCE CHARACTERISTICS

- Analytical sensitivity: 200 ( $\pm$  50) IU/mL, under the described assay conditions
- Prozone effect: No prozone effect was detected up to 1500 IU/mL.
- Diagnostic sensitivity: 98 %.
- Diagnostic specificity: 97 %.

### INTERFERING SUBSTANCES

No interference from:

Bilirubin up to 20mg/dl

Haemoglobin up to 10g/l









Lipids up to 10g/l


RF up to 300IU/ml

### BIBLIOGRAPHY

1. Haffejee . Quarterly Journal of Medicine 1992. New series 84; 305: 641-658.
2. Ahmed Samir et al. Pediatric Annals 1992; 21: 835-842.
3. Spaun J et al. Bull Wld Hlth Org 1961; 24: 271-279. 4. The association of Clinical Pathologists 1961. Broadsheet 34.
5. Picard B et al. La Presse Medicale 1983; 23: 2-6.
6. Klein GC. Applied Microbiology 1971; 21: 999-1001. 7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

### Index of Symbols

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	Catalogue Number		Lot Number
	Store between 2-8°C		Use by
	Manufacturer		Date of manufacture

 Manufactured By:  
Rapid Labs Ltd  
Unit 2 & 2A Hall Farm Business  
Centre Church Road Little Bentley Colchester Essex CO7  
8SD United Kingdom

# ASO Latex Kit Assay

## Anti-Streptolysin O



### CATALOGUE NUMBERS

RL-ASO50      RL-ASO50NA  
RL-ASO100    RL-ASO100NA

### INTENDED USE

The ASO-latex is a slide agglutination test for the qualitative and semiquantitative detection of anti-streptolysin O (ASO) in human serum. Latex particles coated with streptolysin O (SLO) are agglutinated when mixed with samples containing ASO.

### SUMMARY

Streptolysin O is a toxic immunogenic exoenzyme produced by - hemolytic Streptococci of groups A, C and G. Measuring the ASO antibodies are useful for the diagnostic of rheumatoid fever, acute glomerulonephritis and streptococcal infections. Rheumatic fever is an inflammatory disease affecting connective tissue from several parts of human body as (skin, heart, joints, etc...) and acute glomerulonephritis is a renal infection that affects mainly to renal glomerulus.

### MATERIALS

#### Materials provided

Latex	Polystyrene Latex particles coated with Streptolysin O. Sodium Azide: 0.9%
Control + (red cap)	Human Serum based, ASO concentration >250 IU/ML
Control - (green cap)	Human/Animal serum based, ASO negative control Sodium azide <1%

#### Following materials are available with RL-ASO50 & RL-ASO100

##### RL-ASO50

- 5 slide cards
- 50 plastic stirrers

##### RL-ASO100

- 10 slide cards
- 100 plastic stirrers

#### Materials required but not provided

- Mechanical rotor (100 r.p.m)
- Micropipette and tips (50µl)
- Isotonic saline

### PRECAUTIONS

- 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.
- Reagents must be stored between 2-8°C
- Do not freeze
- Store vials upright
- Reagents are provided ready to use.
- Ensure that the reagents are mixed thoroughly before use
- If reagents have particulate matter and aggregates, discard vial and contact Rapid Biotec

### SAMPLE COLLECTION AND PREPARATION

- Use fresh serum
- Serum used must not be haemolysed or contaminated or lipemic as it may affect test results.
- Storage and usage after time serum must be stored at 2-8°C.
- Use serum within 7 days

- For longer storage store at -20°C for 3 months.
- Samples with fibrin should be centrifuged

### CALIBRATION AND TRACEABILITY

Rapid Biotec ASO Visual Latex has been calibrated against NIBSC 64/002.

### LIMITATIONS

- False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsillitis, several streptococcal infections and healthy carriers.
- Early infections and children from 6 months to 5 years may cause false negative results.
- A single ASO determination does not produce much information about the actual state of the disease. Titrations at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

### DIRECTIONS FOR USE

#### Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

#### Semi-quantitative method

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

### INTERPRETATION OF RESULTS

- Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.
- The presence of agglutination indicates an ASO concentration equal or greater than 200 IU/mL.
- The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.
- The approximate ASO concentration in the patient sample is calculated as follows:  
$$200 \times \text{ASO Titer} = \text{IU/mL}$$

### QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

# ASO Latex Kit Assay

## Anti-Streptolysin O



### EXPECTED VALUES

Up to 200 IU/mL(adults) and 100 IU/mL (children < 5 years old). Each laboratory should establish its own reference range.

### PERFORMANCE CHARACTERISTICS

- Analytical sensitivity: 200 ( $\pm$  50) IU/mL, under the described assay conditions
- Prozone effect: No prozone effect was detected up to 1500 IU/mL.
- Diagnostic sensitivity: 98 %.
- Diagnostic specificity: 97 %.

### INTERFERING SUBSTANCES

No interference from:

Bilirubin up to 20mg/dl

Haemoglobin up to 10g/l









Lipids up to 10g/l


RF up to 300IU/ml

### BIBLIOGRAPHY

1. Haffejee . Quarterly Journal of Medicine 1992. New series 84; 305: 641-658.
2. Ahmed Samir et al. Pediatric Annals 1992; 21: 835-842.
3. Spaun J et al. Bull Wld Hlth Org 1961; 24: 271-279. 4. The association of Clinical Pathologists 1961. Broadsheet 34.
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	Catalogue Number		Lot Number
	Store between 2-8°C		Use by
	Manufacturer		Date of manufacture

 Manufactured By:  
Rapid Labs Ltd  
Unit 2 & 2A Hall Farm Business  
Centre Church Road Little Bentley Colchester Essex CO7  
8SD United Kingdom

Doc Ref: ASO Kit RB 1 - 06/2024

# CRP Latex Kit Assay

## C-reactive protein



**RAPID BIOTEC™**



**REF** **IVD** +2°C  +8°C

### CATALOGUE NUMBER

**RL-CRP50 RL-CRP50NA**  
**RL-CRP100 RL-CRP100NA**

### INTENDED USE

The CRP-latex is a slide agglutination test for the qualitative and semiquantitative detection of C- Reactive Protein (CRP) in human serum. Latex particles coated with goat IgG anti-human CRP are agglutinated when mixed with samples containing CRP

### SUMMARY

CRP is an acute-phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise up to 300 mg/L in 12-24 hours.

### MATERIALS

#### **Materials provided**

Latex	Polystyrene Latex particles coated with Anti-Human CRP antibodies Sodium Azide: 0.9%
Control + (red cap)	Human Serum based, CRP concentration >20 mg/IU/ml
Control – (green cap)	Human/Animal serum based, CRP negative control Sodium azide <1%

#### **Following materials are available with RL-CRP50 & RL-CRP100**

<b>RL-CRP50</b>	<b>RL-CRP100</b>
• 5 slide cards	• 10 slide cards
• 50 plastic stirrers	• 100 plastic stirrers

#### **Materials required but not provided**

- Mechanical rotor (100 r.p.m)
- Micropipette and tips (50µl)
- Isotonic saline

### PRECAUTIONS

- 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.
- Reagents must be stored between 2-8°C
- Do not freeze
- Store vials upright
- Reagents are provided ready to use.
- Ensure that the reagents are mixed thoroughly before use
- If reagents have particulate matter and aggregates, discard vial and contact Rapid Biotec

### SAMPLE COLLECTION AND PREPARATION

- Use fresh serum
- Serum used must not be haemolysed or contaminated or lipemic as it may affect test results.
- Storage and usage after time serum must be stored at 2-8°C.
- Use serum within 7 days
- For longer storage store at -20°C for 3 months.
- Samples with fibrin should be centrifuged

### CALIBRATION AND TRACEABILITY

Rapid Biotec CRP latex sensitivity is calibrated to the Reference Material ERMDA 474/IFCC.

### LIMITATIONS

- High CRP concentration samples may give negative results (prozone effect). Re-test the sample again using a drop of 20 µL.
- The strength of agglutination is not indicative of the CRP concentration in the samples tested.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

### DIRECTIONS FOR USE

#### **Qualitative method**

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the CRP-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

#### **Semi-quantitative method**

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method

### INTERPRETATION OF RESULTS

- Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.
- 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.
- The approximate CRP concentration in the patient sample is calculated as follows:  
$$6 \times \text{CRP Titer} = \text{mg/L}$$

### QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

### EXPECTED VALUES

Up to 6 mg/L. Each laboratory should establish its own reference range.

# CRP Latex Kit Assay

## C-reactive protein



**RAPID BIOTEC™**



### PERFORMANCE CHARACTERISTICS

- Analytical sensitivity: 6 (5-10) mg/L, under the described assay conditions
- Prozone effect: No prozone effect was detected up to 1600 IU/mL.
- Diagnostic sensitivity: 95.6 %.
- Diagnostic specificity: 96.2 %.

### INTERFERING SUBSTANCES









No interference from:


- Bilirubin up to 20mg/dl
- Haemoglobin up to 10g/l
- Lipids up to 10g/l
- RF up to 100IU/ml

### BIBLIOGRAPHY

1. Lars-Olof Hanson et al. Current Opinion in Infectious diseases 1997; 10: 196-201.
2. M.M. Pepys. The Lancet 1981; March 21: 653 – 656.
3. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139 – 144.
4. Yoshitsugu Hokama et al. Journal of Clinical Laboratory Status 1987; 1: 15 – 27.
5. Yamamoto S et al. Veterinary Immunology and Immunopathology 1993; 36: 257 – 264.
6. Charles Wadsworth et al. Clinica Chimica Acta; 1984: 138: 309 – 318.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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 Manufactured By:  
Rapid Labs Ltd  
Unit 2 & 2A Hall Farm Business  
Centre Church Road Little Bentley Colchester Essex CO7  
8SD United Kingdom

# CRP Latex Kit Assay

## C-reactive protein



**RAPID BIOTEC™**



**REF** **IVD** +2°C  +8°C

### CATALOGUE NUMBER

**RL-CRP50** **RL-CRP50NA**  
**RL-CRP100** **RL-CRP100NA**

### INTENDED USE

The CRP-latex is a slide agglutination test for the qualitative and semiquantitative detection of C- Reactive Protein (CRP) in human serum. Latex particles coated with goat IgG anti-human CRP are agglutinated when mixed with samples containing CRP

### SUMMARY

CRP is an acute-phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise up to 300 mg/L in 12-24 hours.

### MATERIALS

#### **Materials provided**

Latex	Polystyrene Latex particles coated with Anti-Human CRP antibodies Sodium Azide: 0.9%
Control + (red cap)	Human Serum based, CRP concentration >20 mg/IU/ml
Control – (green cap)	Human/Animal serum based, CRP negative control Sodium azide <1%

#### **Following materials are available with RL-CRP50 & RL-CRP100**

<b>RL-CRP50</b>	<b>RL-CRP100</b>
• 5 slide cards	• 10 slide cards
• 50 plastic stirrers	• 100 plastic stirrers

#### **Materials required but not provided**

- Mechanical rotor (100 r.p.m)
- Micropipette and tips (50µl)
- Isotonic saline

### PRECAUTIONS

- 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.
- Reagents must be stored between 2-8°C
- Do not freeze
- Store vials upright
- Reagents are provided ready to use.
- Ensure that the reagents are mixed thoroughly before use
- If reagents have particulate matter and aggregates, discard vial and contact Rapid Biotec

### SAMPLE COLLECTION AND PREPARATION

- Use fresh serum
- Serum used must not be haemolysed or contaminated or lipemic as it may affect test results.
- Storage and usage after time serum must be stored at 2-8°C.
- Use serum within 7 days
- For longer storage store at -20°C for 3 months.
- Samples with fibrin should be centrifuged

### CALIBRATION AND TRACEABILITY

Rapid Biotec CRP latex sensitivity is calibrated to the Reference Material ERMDA 474/IFCC.

### LIMITATIONS

- High CRP concentration samples may give negative results (prozone effect). Re-test the sample again using a drop of 20 µL.
- The strength of agglutination is not indicative of the CRP concentration in the samples tested.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

### DIRECTIONS FOR USE

#### **Qualitative method**

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the CRP-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

#### **Semi-quantitative method**

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method

### INTERPRETATION OF RESULTS

- Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.
- 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.
- The approximate CRP concentration in the patient sample is calculated as follows:  
$$6 \times \text{CRP Titer} = \text{mg/L}$$

### QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

### EXPECTED VALUES

Up to 6 mg/L. Each laboratory should establish its own reference range.

# CRP Latex Kit Assay

## C-reactive protein



**RAPID BIOTEC™**



### PERFORMANCE CHARACTERISTICS

- Analytical sensitivity: 6 (5-10) mg/L, under the described assay conditions
- Prozone effect: No prozone effect was detected up to 1600 IU/mL.
- Diagnostic sensitivity: 95.6 %.
- Diagnostic specificity: 96.2 %.

### INTERFERING SUBSTANCES









No interference from:


- Bilirubin up to 20mg/dl
- Haemoglobin up to 10g/l
- Lipids up to 10g/l
- RF up to 100IU/ml

### BIBLIOGRAPHY

1. Lars-Olof Hanson et al. Current Opinion in Infectious diseases 1997; 10: 196-201.
2. M.M. Pepys. The Lancet 1981; March 21: 653 – 656.
3. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139 – 144.
4. Yoshitsugu Hokama et al. Journal of Clinical Laboratory Status 1987; 1: 15 – 27.
5. Yamamoto S et al. Veterinary Immunology and Immunopathology 1993; 36: 257 – 264.
6. Charles Wadsworth et al. Clinica Chimica Acta; 1984: 138: 309 – 318.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

### Index of Symbols

	Consult instructions for use		For <i>in vitro</i> diagnostic use only
	Catalogue Number		Lot Number
	Store between 2-8°C		Use by
	Manufacturer		Date of manufacture

 Manufactured By:  
Rapid Labs Ltd  
Unit 2 & 2A Hall Farm Business  
Centre Church Road Little Bentley Colchester Essex CO7  
8SD United Kingdom

# Rheumatoid Factor Latex Kit Assay



## CATALOGUE NUMBER

RL-RA50      RL-RA50NA  
RL-RA100    RL-RA100NA

## INTENDED USE

The RF-latex is a slide agglutination test for the qualitative and semiquantitative detection of RF in human serum. Latex particles coated with human gamma globulin are agglutinated when mixed with samples containing RF.

## SUMMARY

Rheumatoid factors are a group of antibodies directed to determinants in the Fc portion of the immunoglobulin G molecule. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus erythematosus (SLE) and Sjögren's syndrome, as well as in nonrheumatic conditions, its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid arthritis (RA). A study of the "American College of Rheumatology" shows that the 80,4% of RA patients were RF positive.

## MATERIALS

### Materials provided

Latex	Polystyrene Latex particles coated with human gamma globulin. Sodium Azide: 0.9%
Control + (red cap)	Human Serum based, RF concentration >30IU/ml
Control - (green cap)	Human/Animal serum based, RF negative control Sodium azide <1%

### Following materials are available with RL-RA50 & RL-RA100

RL-RA50	RL-RA100
• 5 slide cards	• 10 slide cards
• 50 plastic stirrers	• 100 plastic stirrers

### Materials required but not provided

• Mechanical rotor (100 r.p.m)	• Isotonic saline
• Micropipette and tips (50µl)	

## PRECAUTIONS

- 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.
- Reagents must be stored between 2-8°C
- Do not freeze
- Store vials upright
- Reagents are provided ready to use.
- Ensure that the reagents are mixed thoroughly before use
- If reagents have particulate matter and aggregates, discard vial and contact Rapid Biotec

## SAMPLE COLLECTION AND PREPARATION

- Use fresh serum
- Serum used must not be haemolysed or contaminated or lipemic as it may affect test results.
- Storage and usage after time serum must be stored at 2-8°C.
- Use serum within 7 days
- For longer storage store at -20°C for 3 months.

## CALIBRATION AND TRACEABILITY

The RF-latex sensitivity is calibrated against the RF International Standard from NIBSC 64/002.

## LIMITATIONS

- Results obtained with a latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

## DIRECTIONS FOR USE

### Qualitative method:

1. Allow reagents to reach room temperature before use. Do not use directly from 2-8°C temperature.
2. On a clean slide, place one drop of negative control, positive control and 50µl of patient sample on separate circles.
3. Mix the RF reagent thoroughly (vortex) and add one drop (50µl) to each of the circles.
4. Mix the reagent and the controls/sample drops with a plastic stirrer, ensuring to spread it throughout a 2cm diameter.
5. Place the slide on a mechanical rotor (100 r.p.m) and mix for 2 minutes. Read results macroscopically, do not interpret results after 2 minutes.

### Semi-quantitative method:

1. Prepare serial dilutions of the patient's sample with normal saline (preferable dilution are a double dilution).
2. Follow steps 2 to 5 of the Qualitative method. (negative and positive controls are used neat).

## INTERPRETATION OF RESULTS

- Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.
- The presence of agglutination indicates a RF concentration equal or greater than 8 IU/mL (Note 1).
- The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.
- The approximate RF concentration in the patient sample is calculated as follows:

$$8 \times \text{RF Titer} = \text{IU/mL}$$

## QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of test procedure, as well as a comparative pattern for a better results interpretation. All result different from the negative control result, will be considered as a positive.

## PERFORMANCE CHARACTERISTICS

- Analytical sensitivity: 8 (6-16) IU/mL, under the described assay conditions
  - Prozone effect: No prozone effect was detected up to 1500 IU/mL.
  - Diagnostic sensitivity: 100%.
  - Diagnostic specificity: 100%.
- The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

# Rheumatoid Factor Latex Kit Assay



**RAPID BIOTEC™**



## EXPECTED VALUES

Up to 8 IU/mL. Each laboratory should establish its own reference range.

## INTERFERING SUBSTANCES

No interference from:

Bilirubin up to 20mg/dl









Haemoglobin up to 10g/l


Lipids up to 10g/l

## BIBLIOGRAPHY

1. Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1 – 21.
2. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951- 960.
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 – 534.
4. Adalbert F S et al. The New England Journal of Medicine 1959; 261: 363 – 368.
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 Manufactured By:  
Rapid Labs Ltd  
Unit 2 & 2A Hall Farm Business  
Centre Church Road Little Bentley Colchester Essex CO7  
8SD United Kingdom

Doc Ref: RA Kit RB 1 - 06/2024

# Rheumatoid Factor Latex Kit Assay



## CATALOGUE NUMBER

RL-RA50      RL-RA50NA  
RL-RA100    RL-RA100NA

## INTENDED USE

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  - Diagnostic specificity: 100%.
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# Rheumatoid Factor Latex Kit Assay



**RAPID BIOTEC™**



## EXPECTED VALUES

Up to 8 IU/mL. Each laboratory should establish its own reference range.

## INTERFERING SUBSTANCES

No interference from:

Bilirubin up to 20mg/dl

Haemoglobin up to 10g/l

Lipids up to 10g/l

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Unit 2 & 2A Hall Farm Business  
Centre Church Road Little Bentley Colchester Essex CO7  
8SD United Kingdom

Doc Ref: ASO Kit RB 1 - 06/2024