





biolateX develops and manufactures - OEM, bulk and packed - liquid reagents ready to use for latex enhanced immunnoturbidimetric methods.

The covalent bond between the antigens or antibodies and the micro-particles of latex provides our reagents an excellent accuracy, a high reliability and an up to two years stability.

Strong performance is also assured through the time, following strict manufacturing quality guidelines that allow our reagents obtain similar responses irrespectively of the production batch.

Our commitment with the lab instrument companies and distributors is to meet their needs and establish, if necessary, special contracts for the development and manufacture of reagents.

BI-REAGENT DETERMINATION	SENSITIVITY	REFERENCE RANGE	RANGE UP TO
RHEUMA			
ANTISTREPTOLYSIN O	10 IU/mL	250 IU/mL	900 IU/mL
C-REACTIVE PROTEIN	0.4 mg/L	6-8 mg/L	100 mg/L
RHEUMATOID FACTOR	4.2 IU/mL	20 IU/mL	140 IU/mL
INFLAMATORY STATUS			
ULTRASENSITIVE CRP	0.18 mg/L	6-8 mg/L	$50~\mathrm{mg/L}$
CARDIAC RISK			
CRP CARDIAC MARKER	0.05 mg/L	1-3 mg/L	12.5 mg/L
LIPOPROTEIN (A)	5.0 mg/L	300 mg/L	1200  mg/L
MALNUTRITION STATUS			
RETINOL-BINDING PROTEIN	1.0 mg/L	30-60 mg/L	80 mg/L
RENAL PROFILE			
CYSTATIN C	0.05 mg/L	0.59-1.03 mg/L	10 mg/L
α <sub>1</sub> -MICROGLOBULIN	1.0 mg/L	10 mg/L	90 mg/L
β <sub>2</sub> -MICROGLOBULIN	0.2 mg/L	0.8-2.4 mg/L	12 mg/L
IRON METABOLISM			
FERRITIN	5.2 ng/mL	30-300 ng/mL	500 ng/mL
ALLERGY			
IMMUNOGLOBULIN E	10 IU/mL	0-200 IU/mL	1 <i>5</i> 00 IU/mL
DIABETIC PROFILE			
MICROALBUMIN	3.0 mg/L	0-20 μg/min	250 mg/L
MONOREAGENT DETERMINATION	SENSITIVITY	REFERENCE RANGE	LINEAR RANGE
RHEUMA			
ANTISTREPTOLYSIN O	1 <i>5</i> IU/mL	250 IU/mL	400 IU/mL
C-REACTIVE PROTEIN	2.0 mg/L	6-8 mg/L	90 mg/L
RHEUMATOID FACTOR	10 IU/mL	20 IU/mL	80 IU/mL
CARDIAC RISK			
CRP CARDIAC MARKER	0.05 mg/L	1-3 mg/L	6.5 mg/L
	0.05 mg/L 15 mg/L	1-3 mg/L 300 mg/L	6.5 mg/L 400 mg/L
LIPOPROTEIN (A) RENAL PROFILE			
LIPOPROTEIN (A)  RENAL PROFILE  β <sub>2</sub> -MICROGLOBULIN	15 mg/L	300 mg/L	400 mg/L
LIPOPROTEIN (A)  RENAL PROFILE  β <sub>2</sub> -MICROGLOBULIN  IRON METABOLISM	15 mg/L	300 mg/L	400 mg/L
β <sub>2</sub> -MICROGLOBULIN	15 mg/L 0.2 mg/L	300 mg/L 0.8-2.4 mg/L	400 mg/L 15 mg/L
LIPOPROTEIN (A)  RENAL PROFILE  β <sub>2</sub> -MICROGLOBULIN  IRON METABOLISM  FERRITIN	15 mg/L 0.2 mg/L	300 mg/L 0.8-2.4 mg/L	400 mg/L 15 mg/L

PROZONE >	ASSAY TIME	CALIBRATION	CONTROLS	$R_1 + R_2$	PAGE
1 <i>5</i> 00 IU/mL	7 min	Multipoint	2	6L + 1L	6
200 mg/L	5 min	Multipoint	2	5L + 1L	7
1 <i>5</i> 00 IU/mL	7 min	Multipoint	2	7L + 1L	8
120 mg/L	5 min	Multipoint	2	5L + 1L	9
900 mg/L	5 min	Multipoint	1	5L + 1L	10
2250 mg/L	5 min	Multipoint	1	6L + 1L	11
160 mg/L	5 min	Multipoint	2	5L + 1L	12
16 mg/L	5 min	Multipoint	2	5L + 1L	13
210 mg/L	7 min	Multipoint	1	5L + 1L	14
100 mg/L	4 min	Multipoint	2	5L + 1L	15
5500 ng/mL	4 min	Multipoint	2	3L + 1L	16
12000 IU/mL	4 min	Multipoint	2	3L + 1L	17
500 mg/L	6 min	Multipoint	2	5L + 1L	18
PROZONE >	ASSAY TIME	CALIBRATION	CONTROLS	R, + R2	PAGE
1 <i>5</i> 00 IU/mL	2 min	1 point	1	9L + 1L	19
430 mg/L	2 min	1 point	1	9L + 1L	20
1500 IU/mL	2.5 min	1 point	1	9L + 1L	21
45 mg/L	5 min	1 point	1	9L + 1L	22
2200 mg/L	4 min	1 point	1	7L + 1L	23
100 mg/L	5 min	1 point	1	5L + 1L	24
7000 ng/mL	5 min	1 point	1	2.5L + 1L	25
500 mg/L		1 point	1	9L + 1L	26



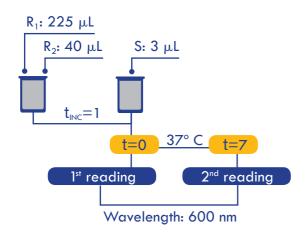
# ANTISTREPTOLYSIN O

- Range of analysis up to 900 IU/mL
- Excellent precisions (n=10):

	1	2	3
Concentration IU/mL	85	200	435
Intra-assay CV %	3.8	2.8	2.7
Inter-assay CV %	4.6	2.7	2.1

- Sensitivity: least detectable dose (n=20) < 10 IU/mL</li>
- Prozone > 1500 IU/mL

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.99 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Traceable to the International Standard for Antistreptolysin-O (WHO).

#### DIAGNOSTIC RELEVANCE

Antistreptolysin O (ASO) testing
is used for the diagnosis of nonsuppurative complications of
infections caused by streptococcal
pathogens: acute rheumatic
fever or acute poststreptococcal
glomerulonephritis.

- ASO and latex particles bound streptolysin O reaction.
- ASO values determined turbidimetrically.

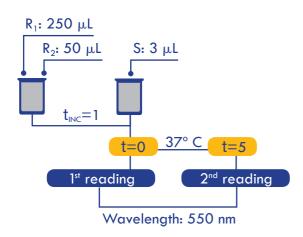
# **C-REACTIVE PROTEIN**

- Range of analysis up to 100 mg/L
- Excellent precisions (n=10):

	1	2	3
Concentration mg/L	5.5	35	60
Intra-assay CV %	2.6	1.9	1.7
Inter-assay CV %	5.0	3.2	5.5

- Sensitivity: least detectable dose (n=20) < 0.4 mg/L</li>
- Prozone > 200 mg/L

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.99 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Traceable to CRM 470 International Standard.

# DIAGNOSTIC RELEVANCE

- Elevated C-reactive Protein (CRP)
  has been demonstrated in nearly all
  bacterial and fungal infections.
- In addition, it has been shown to be increased in other diseases as neoplasia, and rheumatic diseases as well as in major surgery.

- CRP in the sample reaction with latex-covalently bound antibodies against human CRP.
- CRP values determined turbidimetrically.



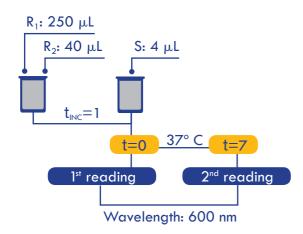
# RHEUMATOID FACTOR

- Range of analysis up to 140 IU/mL
- Excellent precisions (n=10):

	1	2	3
Concentration IU/mL	40	70	125
Intra-assay CV %	2.3	1.6	2.3
Inter-assay CV %	5.6	2.3	

- Sensitivity: least detectable dose (n=20) < 4.2 IU/mL</li>
- Prozone > 1500 IU/mL

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.97 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Standardized against the International Reference Preparation of Rheumatoid Arthritis Serum (WHO).

#### DIAGNOSTIC RELEVANCE

Rheumatoid Factors (RF)
 determinations are clinically important
 for the diagnosis, prognosis and
 assessment of therapeutic efficacy of
 rheumatoid arthritis.

#### MEASURING METHOD

- IgM-anti-IgG (RF) and latexcovalently bound human IgG reaction.
- RF values determined turbidimetrically.

<u>biolatex</u>

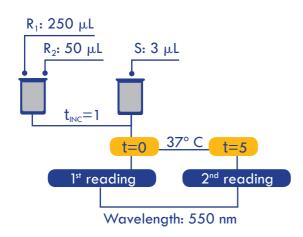
# **ULTRASENSITIVE CRP**

- Range of analysis up to 50 mg/L
- Excellent precisions (n=10):

	1	2	3
Concentration mg/L	1.75	5.5	40
Intra-assay CV %	5.2	3.2	2.3
Inter-assay CV %	4.2	2.0	5.6

- Sensitivity: least detectable dose (n=20) < 0.18 mg/L</li>
- Prozone > 120 mg/L

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 1.00 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Traceable to CRM 470 International Standard.

#### DIAGNOSTIC RELEVANCE

- Elevated C-reactive Protein (CRP)
  has been demonstrated in nearly all
  bacterial and fungal infections.
- In addition, it has been shown to be increased in other diseases as neoplasia, and rheumatic diseases as well as in major surgery.

- CRP in the sample reaction with latex-covalently bound antibodies against human CRP.
- CRP values determined turbidimetrically.

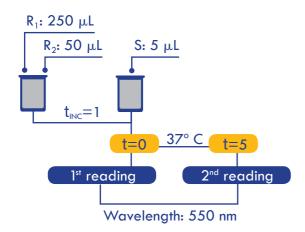
# CRP CARDIAC MARKER

- Range of analysis up to 12.5 mg/L
- Excellent precisions (n=10):

	1	2	3
Concentration mg/L	0.6	1.1	2.1
Intra-assay CV %	9.2	2.6	2.8
Inter-assay CV %	6.8	3.4	3.2

- Sensitivity: least detectable dose (n=20) < 0.05 mg/L</li>
- Prozone > 900 mg/L

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.99 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Traceable to CRM 470 International Standard.

#### DIAGNOSTIC RELEVANCE

- C-reactive Protein (CRP) is a marker of inflammation that seems to be a strong predictor of cardiovascular events and has been used to predict incident myocardial infarction, stroke, peripheral arterial disease and sudden cardiac death.
- The addition of CRP to standard cholesterol evaluation may thus provide a simple and inexpensive method to improve global risk prediction and compliance with preventive approaches.

- CRP in the sample reaction with latexcovalently bound antibodies against human CRP.
- CRP values determined turbidimetrically.

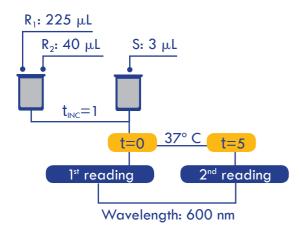
# LIPOPROTEIN (A)

- Range of analysis up to 1200 mg/L
- Excellent precisions (n=10):

	1	2	3
Concentration mg/L	160	479	715
Intra-assay CV %	4.7	4.5	3.4
Inter-assay CV %	5.1	3.9	3.5

- Sensitivity: least detectable dose (n=20) < 5.0 mg/L</li>
- Prozone > 2250 mg/L

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.96 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Standardized against WHO reference material SRM2B.

#### DIAGNOSTIC RELEVANCE

- High lipoprotein(a) [Lp(a)]
   concentration is associated with risk
   for cardiovascular disease and also
   associated with an increased risk of
   coronary heart disease.
- Quantitation of Lp(a) is important for identification of individuals at risk for developing atherosclerosis.

- Lp(a) in the sample and latexcovalently bound antibodies against human Lp(a) reaction.
- Lp(a) values determined turbidimetrically.

# BI-REAGENT

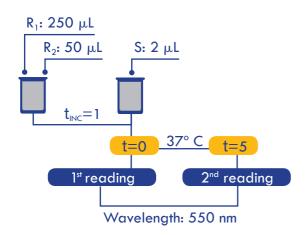
# RETINOL-BINDING PROTEIN

- Range of analysis up to 80 mg/L
- Excellent precisions (n=10):

	1	2	3
Concentration mg/L	1 <i>7</i>	33	60
Intra-assay CV %	2.2	0.8	1.5
Inter-assay CV %	2.7	2.1	3.7

- Sensitivity: least detectable dose (n=20) < 1.0 mg/L</li>
- Prozone > 160 mg/L

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.99 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Standardized against a highly purified material.

#### DIAGNOSTIC RELEVANCE

- Retinol-binding Protein (RBP)
   concentrations are markedly
   disminished in malnutrition and other
   conditions.
- Due to its short half live may be suitable for monitoring the nutritional status and efficacy of parenteral nutrition.

- RBP and latex-covalently bound antibodies against human RBP reaction.
- RBP values determined turbidimetrically.

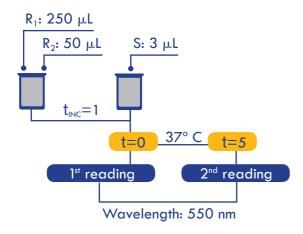
# CYSTATIN C

- Range of analysis up to 10 mg/L
- Excellent precisions (n=10):

	-1	2	3	4
Concentration mg/L	0.85	1.5	3.0	5.0
Intra-assay CV %	1.0	1.2	1.0	0.7
Inter-assay CV %	3.4	2.2	1.5	2.9

- Sensitivity: least detectable dose (n=20) < 0.05 mg/L</li>
- Prozone > 16 mg/L

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.99 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Standardized against IFCC human serum ERM-DA471.

#### **DIAGNOSTIC RELEVANCE**

- Cystatin C is an excellent indicator of GFR (glomerular filtration rate) as its concentration is almost exclusively determined by the GFR.
- Cystatin C is also acknowledged as a marker of elevated risk of death from cardiovascular complications – myocardial infarction and stroke.

- Cystatin C and latex-covalently bound antibodies against human Cystatin C reaction.
- Cystatin C values determined turbidimetrically.



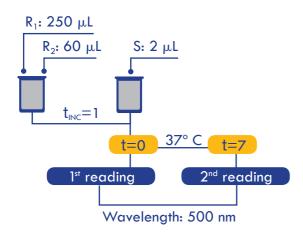
# $\alpha_1$ -MICROGLOBULIN

- Range of analysis up to 90 mg/L
- Excellent precisions (n=10):

	1	2	3
Concentration mg/L	16	28	40
Intra-assay CV %	2.4	3.9	3.1
Inter-assay CV %	2.8	4.3	5.2

- Sensitivity: least detectable dose (n=20) < 1.0 mg/L</li>
- Prozone > 210 mg/L

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.98 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Standardized with reference to highly purified proteins preparation.

#### DIAGNOSTIC RELEVANCE

• Elevated concentrations of low molecular weight proteins in urine such as  $\alpha_1$ - microglobulin indicates tubular damage, which can occur after heavy metal exposure or in the course of advanced diabetic nephropathy, nephritis or others pathologies.

- Antibody to human  $\alpha_1$  microglobulin bound to latex particles reaction with  $\alpha_1$  microglobulin in a sample.
- $\alpha_1$  microglobulin values determined turbidimetrically.

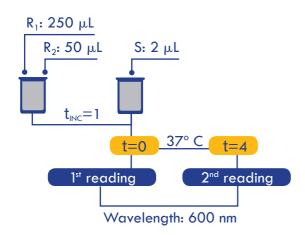
# $\beta_{\text{g}}$ -MICROGLOBULIN

- Range of analysis up to 12 mg/L
- Excellent precisions (n=10):

	1	2	3
Concentration mg/L	1.8	5.8	11.5
Intra-assay CV %	2.3	2.2	2.1
Inter-assay CV %	4.1	3.9	7.5

- Sensitivity: least detectable dose (n=20) < 0.2 mg/L</li>
- Prozone > 100 mg/L

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.99 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Standardized with reference to highly purified proteins preparation.

#### DIAGNOSTIC RELEVANCE

- Increased urinary excretion of  $\beta_2$ microglobulin is an indicator of renal
  tubular disorders used to detect early
  nephotoxicity in patients treated with
  gentamicin and other nephrotoxic drugs.
- Elevated serum levels has been reported as a useful marker of Acquired Immune Deficiency Syndrome, in myeloma patients and in a variety of diseases including carcinomas and lymphoid tumours and inflammatory and autoimmune diseases.

- $\beta_2$ -microglobulin in the sample reaction with latex-covalently bound antihuman  $\beta_2$ -microglobulin antibodies.
- β<sub>2</sub>-microglobulin values determined turbidimetrically.

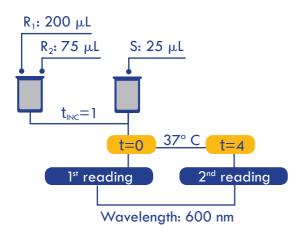
# **FERRITIN**

- Range of analysis up to 500 ng/mL
- Excellent precisions (n=10):

	1	2
Concentration ng/mL	180	285
Intra-assay CV %	1.6	1.6
Inter-assay CV %	3.3	3.2

- Sensitivity: least detectable dose (n=20) < 5.2 ng/mL</li>
- Prozone > 5500 ng/mL

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 1.00 with another commercial procedure.
- Long self-life up to 18 months, liquid reagents ready to use.
- Traceable to WHO 80/578 International Standard.

#### DIAGNOSTIC RELEVANCE

- Ferritin concentration is correlated with the quantity of available iron stored in the body so its determination is used for diagnosis and monitoring of iron deficiency and iron overload.
- Concentrations of Ferritin are found to be elevated in patients with infections, inflammation or in hepatic or chronic renal diseases.

- Ferritin in the sample and latexcovalently bound antibodies against human Ferritin reaction.
- Ferritin values determined turbidimetrically.

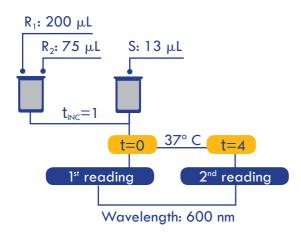
# IMMUNOGLOBULIN E

- Range of analysis up to 1500 IU/mL
- Excellent precisions (n=10):

	1	2	3
Concentration IU/mL	40	80	140
Intra-assay CV %	3.3	1.6	1.3
Inter-assay CV %	4.7	3.4	1.5

- Sensitivity: least detectable dose (n=20) < 10 IU/mL</li>
- Prozone > 12000 IU/mL

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 1.00 with another commercial procedure.
- Long self-life up to 1 year, liquid reagents ready to use.
- Standardized against IRP 75/502.

#### DIAGNOSTIC RELEVANCE

- Immunoglobulin (IgE) determinations are indicated in the diagnosis and monitoring of allergic diseases.
- Elevated IgE levels also occur in parasitosis and immunodeficiency syndromes.
- In infants and small children with recurrent respiratory tract diseases the determination of IgE is of prognostic relevance, and also in some myelomas of IgE type.

- Anti-IgE antibodies covalently bound to latex particles reaction with the IgE in the sample.
- IgE values determined turbidimetrically.

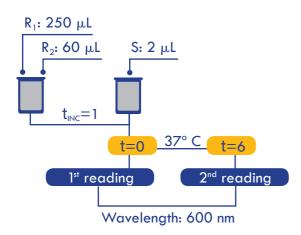
# MICROALBUMIN

- Range of analysis up to 250 mg/L
- Excellent precisions (n=10):

	1	2	3
Concentration mg/L	20	55	115
Intra-assay CV %	0.8	0.6	1.1
Inter-assay CV %	6.3	1.9	4.1

- Sensitivity: least detectable dose (n=20) < 3.0 mg/L</li>
- Prozone > 500 mg/L

# **GENERAL APLICATION**



Volume, time and wavelength are recommended and may be adjusted depending on the analyzer features.

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.98 with another commercial procedure.
- Long self-life up to 2 yearss, liquid reagents ready to use.
- Traceable to CRM 470 International Standard.

# DIAGNOSTIC RELEVANCE

- Elevations in the albumin excretion has been used as a predictor of nephropathy and cardiovascular disease in diabetic patients.
- It has also been associated with hypertension and increased risk of cardiovascular disease in nondiabetic patients.

- Sample albumin reaction with latex enhanced albumin antibody.
- Microalbumin concentration determined turbidimetrically.



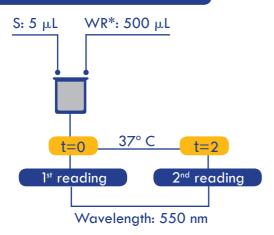
# ANTISTREPTOLYSIN O

- Range of analysis up to 900 IU/mL (linear up to 400 IU/mL)
- Excellent precisions (n=10):

	1	2	3
Concentration IU/mL	100	200	430
Intra-assay CV %	2.9	3.1	2.9
Inter-assay CV %	2.9	3.6	4,4

- Sensitivity: least detectable dose (n=20) < 15 IU/mL</li>
- Prozone > 1500 IU/mL

# **GENERAL APLICATION**



(\*) Working Reagent (WR)

1 part of reagent latex +

9 parts of reagent buffer

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric monoreagent method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.99 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Traceable to the International Standard for Antistreptolysin-O (WHO).

#### DIAGNOSTIC RELEVANCE

Antistreptolysin O (ASO) testing
is used for the diagnosis of nonsuppurative complications of
infections caused by streptococcal
pathogens: acute rheumatic
fever or acute poststreptococcal
glomerulonephritis.

- ASO and latex particles bound streptolysin O reaction.
- ASO values determined photometrically.



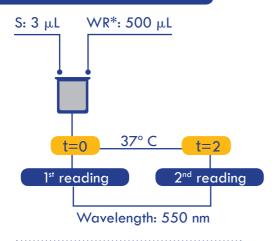
# **C-REACTIVE PROTEIN**

- Range of analysis up to 90 mg/L (linear up to 90 mg/L)
- Excellent precisions (n=10):

	- 1	2	3
Concentration mg/L	8	18	33
Intra-assay CV %	2.8	3.2	4.2
Inter-assay CV %	3.9	4.1	4.6

- Sensitivity: least detectable dose (n=20) < 2.0 mg/L</li>
- Prozone > 430 mg/L

# **GENERAL APLICATION**



(\*) Working Reagent (WR)

1 part of reagent latex +

9 parts of reagent buffer

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric monoreagent method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.99 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Traceable to CRM 470 International Standard.

#### DIAGNOSTIC RELEVANCE

- Elevated C-reactive Protein (CRP)
   has been demonstrated in nearly all
   bacterial and fungal infections.
- In addition, it has been shown to be increased in other diseases as neoplasia, and rheumatic diseases as well as in major surgery.

- CRP in the sample reaction with latex-covalently bound antibodies against human CRP.
- CRP values determined photometrically.



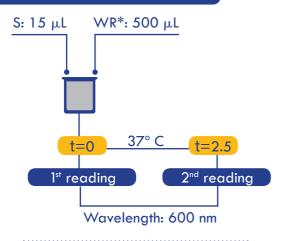
# RHEUMATOID FACTOR

- Range of analysis up to 200 IU/mL (linear up to 80 IU/mL)
- Excellent precisions (n=10):

	1	2	3
Concentration IU/mL	1 <i>7</i>	70	120
Intra-assay CV %	4.7	2.6	2.1
Inter-assay CV %	2.5	3.8	2.3

- Sensitivity: least detectable dose (n=20) < 10 IU/mL</li>
- Prozone > 1500 IU/mL

# **GENERAL APLICATION**



(\*) Working Reagent (WR)1 part of reagent latex +

9 parts of reagent buffer

# MAIN FEATURES

- Latex enhanced immunoturbidimetric monoreagent method.
- Easy to program on any type of automated analyzers.
- Long self-life up to 2 years, liquid reagents ready to use.
- Standardized against the International Reference Preparation of Rheumatoid Arthritis Serum (WHO).

### DIAGNOSTIC RELEVANCE

Rheumatoid Factors (RF)
 determinations are clinically
 important for the diagnosis,
 prognosis and assessment of
 therapeutic efficacy of rheumatoid
 arthritis.

# MEASURING METHOD

- IgM-anti-IgG (RF) and latexcovalently bound human IgG reaction.
- RF values determined photometrically.

<u>biolatex</u>



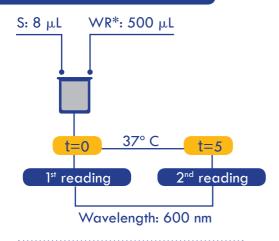
# CRP CARDIAC MARKER

- Range of analysis up to 12.5 mg/L (linear up to 6.5 mg/L)
- Excellent precisions (n=10):

	1	2	3
Concentration mg/L	0.75	1.5	3.0
Intra-assay CV %	2.3	2.4	1.6
Inter-assay CV %	2.5	2.0	1.6

- Sensitivity: least detectable dose (n=20) < 0.05 mg/L</li>
- Prozone > 45 mg/L

# **GENERAL APLICATION**



(\*) Working Reagent (WR)

1 part of reagent latex +

9 parts of reagent buffer

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric monoreagent method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.98 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Traceable to CRM 470 International Standard.

#### DIAGNOSTIC RELEVANCE

- C-reactive Protein (CRP) is a marker of inflammation that seems to be a strong predictor of cardiovascular events and has been used to predict incident myocardial infarction, stroke, peripheral arterial disease and sudden cardiac death.
- The addition of CRP to standard cholesterol evaluation may thus provide a simple and inexpensive method to improve global risk prediction and compliance with preventive approaches.

- CRP in the sample reaction with latexcovalently bound antibodies against human CRP.
- CRP values determined photometrically.

# • • MONOREAGENT

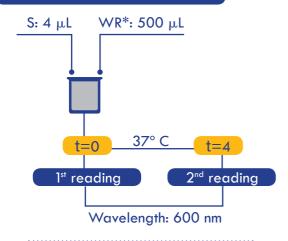
# LIPOPROTEIN (A)

- Range of analysis up to 900 mg/L (linear up to 400 mg/L)
- Excellent precisions (n=10):

	- 1	2	3
Concentration mg/L	90	170	325
Intra-assay CV %	1. <i>7</i>	2.0	4.4
Inter-assay CV %	3.3	1.7	4.8

- Sensitivity: least detectable dose (n=20) < 15 mg/L</li>
- Prozone > 2200 mg/L

# **GENERAL APLICATION**



(\*) Working Reagent (WR)

1 part of reagent latex +

7 parts of reagent buffer

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric monoreagent method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.99 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Standardized against WHO reference material SRM2B.

#### DIAGNOSTIC RELEVANCE

- High lipoprotein(a) [Lp(a)] concentration is associated with risk for cardiovascular disease and also associated with an increased risk of coronary heart disease.
- Quantitation of Lp(a) is important for identification of individuals at risk for developing atherosclerosis.

- Lp(a) in the sample and latex-covalently bound antibodies against human Lp(a) reaction.
- Lp(a) values determined photometrically.

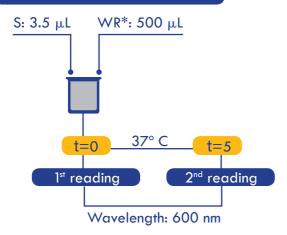
# Ba-MICROGLOBULIN

- Range of analysis up to 20 mg/L (linear up to 15 mg/L)
- Excellent precisions (n=10):

	- 1	2	3
Concentration mg/L	1.75	8	15
Intra-assay CV %	3.2	1.3	1.9
Inter-assay CV %	3.0	1.8	4.2

- Sensitivity: least detectable dose (n=20) < 0.2 mg/L</li>
- Prozone > 100 mg/L

# **GENERAL APLICATION**



(\*) Working Reagent (WR)

1 part of reagent latex +

5 parts of reagent buffer

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric monoreagent method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 1.00 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Standardized with reference to highly purified proteins preparation.

#### DIAGNOSTIC RELEVANCE

- Increased urinary excretion of  $\beta_2$ microglobulin is an indicator of renal
  tubular disorders used to detect early
  nephotoxicity in patients treated with
  gentamicin and other nephrotoxic drugs.
- Elevated serum levels has been reported as a useful marker of Acquired Immune Deficiency Syndrome, in myeloma patients and in a variety of diseases including carcinomas and lymphoid tumours and inflammatory and autoimmune diseases.

- $\beta_2$ -microglobulin in the sample reaction with latex-covalently bound antihuman  $\beta_2$ -microglobulin antibodies.
- β<sub>2</sub>-microglobulin values determined photometrically.

# • • MONOREAGENT

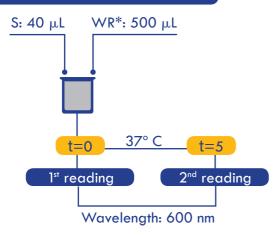
# **FERRITIN**

- Range of analysis up to 500 ng/mL (linear up to 300 ng/mL)
- Excellent precisions (n=10):

	1	2	3
Concentration ng/mL	37	170	270
Intra-assay CV %	3.4	1.4	1.0
Inter-assay CV %	3.9	1.7	1.3

- Sensitivity: least detectable dose (n=20) < 5.0 ng/mL</li>
- Prozone > 7000 ng/mL

# **GENERAL APLICATION**



(\*) Working Reagent (WR)

1 part of reagent latex +

2.5 parts of reagent buffer

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric monoreagent method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.95 with another commercial procedure.
- Long self-life up to 18 months, liquid reagents ready to use.
- Traceable to WHO 80/578 International Standard.

#### DIAGNOSTIC RELEVANCE

- Ferritin concentration is correlated with the quantity of available iron stored in the body so its determination is used for diagnosis and monitoring of iron deficiency and iron overload.
- Concentrations of Ferritin are found to be elevated in patients with infections, inflammation or in hepatic or chronic renal diseases.

- Ferritin in the sample and latexcovalently bound antibodies against human Ferritin reaction.
- Ferritin values determined photometrically.

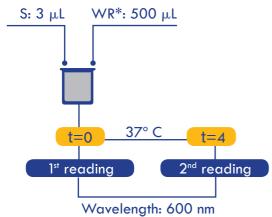
# MICROALBUMIN

- Range of analysis up to 250 mg/L (linear up to 125 mg/L)
- Excellent precisions (n=10):

	- 1	2	3
Concentration mg/L	30	60	160
Intra-assay CV %	3.4	3.7	1.9
Inter-assay CV %	4.5	2.4	4.5

- Sensitivity: least detectable dose (n=20) < 5.0 mg/L</li>
- Prozone > 500 mg/L

# **GENERAL APLICATION**



(\*) Working Reagent (WR)

1 part of reagent latex +

9 parts of reagent buffer

#### MAIN FEATURES

- Latex enhanced immunoturbidimetric monoreagent method.
- Easy to program on any type of automated analyzers.
- Correlation coeficient of 0.98 with another commercial procedure.
- Long self-life up to 2 years, liquid reagents ready to use.
- Traceable to CRM 470 International Standard.

#### DIAGNOSTIC RELEVANCE

- Elevations in the albumin excretion has been used as a predictor of nephropathy and cardiovascular disease in diabetic patients.
- It has also been associated with hypertension and increased risk of cardiovascular disease in non-diabetic patients.

- Sample albumin reaction with latex enhanced albumin antibody.
- Microalbumin concentration determined photometrically.





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