

# α-AMYLASE

Continuous-spectrophotometric  
DIRECT SUBSTRATE

## Instrument: OPERA

### Principle of the method

α-Amylase catalyzes the hydrolysis of 2-chloro-4-nitrophenyl-maltotrioside (CNP-G3) to 2-chloro-4-nitrophenol (CNP). The catalytic concentration is determined from the rate of 2-chloro-4-nitrophenol formation, measured at 405 nm.

### Samples

Serum, plasma, urine.

α-Amylase in serum, plasma or urine is stable for 5 days at 2-8°C.  
Heparin may be used as anticoagulant.

### Reagent preparation

Reagent is ready to use.

### Performance characteristics

- Linearity: up to 1300 U/L (serum) or 2600 U/L (urine).
- Interferences: Fluoride, oxalate, citrate and EDTA as anticoagulants interfere.

## Instrument settings

CHEM. #	(*)
NAME	AMYL IFCC
IMMUNOASSAY	NO
TYPE	ZERO ORDER
INVERSE	NO
% SAMPLE VOL.	12 (6 $\mu$ L)
FILTER P.	405
BIC. CHEM.	NO
DELAY TIME	0:30
BLANK	NO
% REAGENT VOL.	60 (300 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	U/L
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.210
RBL. HIGH	0.700
RANGE LOW	0.0
RANGE HIGH	1300
CAL. FACTOR (**)	4703
REAGENT RATE	0.000
NORMAL LOW	0.0
NORMAL HIGH	60.0
SLOPE	1.00
INTERCEPTION	0:00
C1*10E-6	0.00
C2*10E-6	99999
D1*10E-6	10.00
DELTA#	0.010
	(*) Data entered by the operator (**) CAL. FACTOR is determined by a calibration assay

# ASPARTATE AMINOTRANSFERASE (AST/GOT)

Continuous-spectrophotometric  
IFCC

## Instrument: OPERA

### Principle of the method

Aspartate aminotransferase (AST or GOT) catalyzes the transfer of the amino group from aspartate to 2-oxoglutarate, forming oxalacetate and glutamate. The catalytic concentration is determined from the rate of decrease of NADH, measured at 340 nm, by means of the malate dehydrogenase (MDH) coupled reaction.

### Samples

Serum.  
Aspartate aminotransferase in serum is stable for 7 days at 2-8°C.

### Reagent preparation

Working Reagent: Pour the contents of the Reagent B into the Reagent A bottle. Mix gently.  
Stable for 2 months at 2-8°C.

### Performance characteristics

- Linearity: up to 500 U/L.

### Instrument settings

CHEM. #	(*)
NAME	AST
IMMUNOASSAY	NO
TYPE	ZERO ORDER
INVERSE	YES
% SAMPLE VOL.	30 (15 $\mu$ L)
FILTER P.	340
BIC. CHEM.	NO
DEPLETION LIMIT	0.200
DELAY TIME	0:30
BLANK	NO
% REAGENT VOL.	60 (300 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	U/L
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.7
RANGE LOW	0.0
RANGE HIGH	500
CAL. FACTOR (**)	4761
REAGENT RATE	0.000
NORMAL LOW	0.0
NORMAL HIGH	42
SLOPE	1.00
INTERCEPTION	0:00
C1*10E-6	0.00
C2*10E-6	99999
D1*10E-6	10.00
DELTA#	0.010
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay

# DIRECT BILIRUBIN

Spectrophotometric  
DIAZOTIZED SULFANILIC

## Instrument: OPERA

### Principle of the method

Direct bilirubin in the sample reacts with diazotized sulfanilic acid forming a coloured complex that can be measured by spectrophotometry. The terms "direct" and "total" refer to the reaction characteristics of serum bilirubin in the absence or presence of solubilizing (accelerating) reagents, and are only approximately equivalent to the conjugated and unconjugated fractions.

### Samples

Serum.

Stable for 2 days at 2-8°C and protected from light.

### Reagent preparation

Reagent 1: Use the Reagent A-D.

Reagent 2: Use the Reagent B.

### Performance characteristics

- Linearity: up to 15 mg/dL.

### Instrument settings

CHEM. #	(*)
NAME	BIL-D
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	60 (30 <input type="checkbox"/> )
FILTER P.	550
BIC. CHEM.	NO
DELAY TIME	2:00
BLANK TYPE	DEFAULT
% REAGENT VOL.	60 (300 <input type="checkbox"/> )
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	15 (75 <input type="checkbox"/> )
A2 DELAY	2:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	2
RBL. LOW	0.000
RBL. HIGH	0.040
RANGE LOW	0.00
RANGE HIGH	15.0
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0.000
NORMAL LOW	0.0
NORMAL HIGH	0.25
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.050
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

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# BILIRUBIN (TOTAL)

Spectrophotometric  
DIAZOTIZED SULFANILIC

## Instrument: OPERA

### Principle of the method

Total bilirubin in the sample reacts with diazotized sulfanilic in acid medium forming a coloured complex that can be measured by spectrophotometry. Both direct (conjugated with glucuronate) and indirect (unconjugated) bilirubin couple with diazo in the presence of cetrimide. The terms "direct" and "total" refer to the reaction characteristics of serum bilirubin in the absence or presence of solubilizing (accelerating) reagents, and are only approximately equivalent to the conjugated and unconjugated fractions.

### Samples

Serum.

Stable for 2 days at 2-8°C and protected from light.

### Reagent preparation

Reagent 1: Use the Reagent A-T.

Reagent 2: Use the Reagent B.

### Performance characteristics

- Linearity: up to 15 mg/dL.

## Instrument settings

CHEM. #	(*)
NAME	BIL-T
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	60 (30 <input type="checkbox"/> L)
FILTER P.	550
BIC. CHEM.	NO
DELAY TIME	2:00
BLANK TYPE	DEFAULT
% REAGENT VOL.	60 (300 <input type="checkbox"/> L)
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT VOL.	15 (75 <input type="checkbox"/> L)
A2 DELAY	2:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	2
RBL. LOW	0.000
RBL. HIGH	0.040
RANGE LOW	0.00
RANGE HIGH	15.0
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0.000
NORMAL LOW	0.10
NORMAL HIGH	1.10
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.050
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# CALCIUM

Spectrophotometric  
METHYLTHYMOL BLUE

## Instrument: OPERA

### Principle of the method

Calcium in the sample reacts with methylthymol blue in alkaline medium forming a coloured complex that can be measured by spectrophotometry. Hydroxyquinoleine is included in the reagent to remove magnesium interference.

### Samples

Serum, heparinized plasma, urine.

Calcium in serum or plasma is stable for 10 days at 2-8°C.

Anticoagulants other than heparin should not be used.

### Reagent preparation

Working Reagent: Mix equal volumes of Reagent A and Reagent B. Mix thoroughly.

Stable for 2 days at 2-8°C.

### Performance characteristics

- Linearity: up to 15 mg/dL.
- Interferences: Hemoglobin (1.5 g/L), magnesium (10 mg/dL), phosphate (20 mg/dL) and bilirubin (20 mg/dL) do not interfere.

## Instrument settings

CHEM. #	(*)
NAME	CA MTB
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	7 (3.5 $\mu$ L)
FILTER P.	600
BIC. CHEM.	NO
DELAY TIME	2:00
BLANK TYPE	NO
% REAGENT VOL.	70 (350 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	1
RBL. LOW	0.000
RBL. HIGH	0.350
RANGE LOW	0.00
RANGE HIGH	15.0
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0.000
NORMAL LOW	9.0
NORMAL HIGH	10.7
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.020
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# CHOLESTEROL

Enzymatic-spectrophotometric  
CHOLESTEROL OXIDASE/PEROXIDASE

## Instrument: OPERA

### Principle of the method

Free and esterified cholesterol in the sample originates, by means of some coupled reactions, a coloured complex that can be measured by spectrophotometry.

### Samples

Serum, plasma.

Stable for 7 days at 2-8°C.

Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

### Reagent preparation

Reagent is ready to be used.

### Performance characteristics

- Linearity: up to 1000 mg/dL.
- Interferences: Hemoglobin (3 g/L), bilirubin (0.25 mmol/L) and ascorbic acid interfere. Lipemia does not affect results.

## Instrument settings

CHEM. #	(*)
NAME	CHOL
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	7 (3.5 $\mu$ L)
FILTER P.	500
BIC. CHEM.	NO
DELAY TIME	3:00
BLANK TYPE	NO
% REAGENT VOL.	70 (350 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	1
RBL. LOW	0.000
RBL. HIGH	0.040
RANGE LOW	0.00
RANGE HIGH	800
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0.000
NORMAL LOW	123
NORMAL HIGH	270
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.010
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# CREATINE KINASE (CK)

Continuous-spectrophotometric  
IFCC

## Instrument: OPERA

### Principle of the method

Creatine kinase (CK) catalyzes the phosphorylation of ADP, in the presence of creatine phosphate, to form ATP and creatine. The catalytic concentration is determined from the rate of NADPH formation, measured at 340 nm, by means of the hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6P-DH) coupled reactions.

### Samples

Serum.

Creatine kinase in serum is stable for 7 days at 2-8°C.

### Reagent preparation

Working Reagent: Reconstitute the contents of a Reagent B vial with 2.5 mL (if 20 x 2.5 mL size) or 15 mL (if 10 x 15 mL size) of Reagent A. Swirl gently. Stable for 15 days at 2-8°C.

### Performance characteristics

- Linearity: up to 900 U/L.

## Instrument settings

CHEM. #	(*)
NAME	CK
IMMUNOASSAY	NO
TYPE	ZERO ORDER
INVERSE	NO
% SAMPLE VOL.	24 (12 $\mu$ L)
FILTER P.	340
BIC. CHEM.	NO
DELAY TIME	3:15
BLANK	NO
% REAGENT VOL.	60 (300 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	U/L
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.0
RBL. HIGH	0.400
RANGE LOW	0.0
RANGE HIGH	2400
CAL. FACTOR (**)	5896
REAGENT RATE	0.000
NORMAL LOW	24
NORMAL HIGH	195
SLOPE	1.00
INTERCEPTION	0:00
C1*10E-6	0.00
C2*10E-6	99999
D1*10E-6	10.00
DELTA#	0.010
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay

# CREATINE KINASE-MB (CK-MB)

Immunoinhibition

## Instrument: OPERA

### Principle of the method

A specific antibody inhibits both M subunits of CK-MM (CK-3), and the single M subunit of CK-MB (CK-2) and thus allow determination of the B subunit of CK-MB (assuming the absence of CK-BB or CK-1). CK-B catalytic concentration, which corresponds to half of CK-MB concentration, is determined from the rate of NADPH formation, measured at 340 nm, by means of the hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6P-DH) coupled reactions.

### Samples

Serum.

CK-MB in serum is stable for 7 days at 2-8°C.

### Reagent preparation

Working Reagent: Reconstitute the contents of a Reagent B vial with 2.5 mL (if 20x2.5 mL size) or 10 mL (if 10x10 mL size) of Reagent A. Mix gently.

Stable for 15 days at 2-8°C.

### Performance characteristics

- Linearity: up to 330 U/L.

## Instrument settings

CHEM. #	(*)
NAME	CK-MB
IMMUNOASSAY	NO
TYPE	ZERO ORDER
INVERSE	NO
% SAMPLE VOL.	24 (12 $\mu$ L)
FILTER P.	340
BIC. CHEM.	NO
DELAY TIME	5:00
BLANK	NO
% REAGENT VOL.	60 (300 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	U/L
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.0
RBL. HIGH	0.400
RANGE LOW	0.0
RANGE HIGH	650
CAL. FACTOR (**)	2948
REAGENT RATE	0.000
NORMAL LOW	0
NORMAL HIGH	12
SLOPE	1.00
INTERCEPTION	0:00
C1*10E-6	0.00
C2*10E-6	99999
D1*10E-6	10.00
DELTA#	0.010
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay

# CREATININE

Kinetic-spectrophotometric  
ALKALINE PICRATE

## Instrument: OPERA

### Principle of the method

Creatinine in the sample reacts with picrate in alkaline medium forming a coloured complex. The complex formation rate is measured in a short period to avoid interferences.

### Samples

Serum, plasma, urine.

Creatinine in serum or plasma is stable for 24 hours at 2-8°C.

Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

### Reagent preparation

Working Reagent: Mix equal volumes of Reagent A and Reagent B. Mix thoroughly.

Stable for 2 months at 2-8°C.

### Performance characteristics

- Linearity: up to 20 mg/dL.
- Interferences: Hemoglobin (0.1 g/L), bilirubin (10 mg/dL), protein and ketonic bodies do not interfere.

### Instrument settings

CHEM. #	(*)
NAME	CREA
IMMUNOASSAY	NO
TYPE	FIRST ORDER
INVERSE	NO
% SAMPLE VOL.	60 (30 $\mu$ L)
FILTER P.	500
DELAY TIME	0:30
INCUBATE	1:00
% REAGENT VOL.	60 (300 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	1
RBL. LOW	0.000
RBL. HIGH	0.300
RANGE LOW	0.00
RANGE HIGH	20.0
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0
NORMAL LOW	0.5
NORMAL HIGH	1.10
SLOPE	1.00
INTERCEPTION	0.00
LINEAR FACTOR	2.65
FIRST LIMIT	0.010
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# FRUCTOSAMINE

Kinetic-spectrophotometric  
NBT

## Instrument: OPERA

### Principle of the method

Serum glycated proteins reduce nitroblue tetrazolium (NBT) salts in alkaline medium. The rate of formazan formation at a given temperature is proportional to the serum concentration of glycated proteins.

### Samples

Serum.

Stable for 1 week at 2-8°C and for 2 months at -20°C.

Hemolysed samples are not suitable for testing.

### Reagent preparation

Reagent is ready to be used.

### Performance characteristics

- Linearity: up to 7 mmol/L.
- Interferences: Hemoglobin (up to 100 mg/dL), uric acid (up to 15 mg/dL), lipidemia and bilirubin (up to 2 mg/dL) do not interfere.

### Instrument settings

CHEM. #	(*)
NAME	FRUC
IMMUNOASSAY	NO
TYPE	FIRST ORDER
INVERSE	NO
% SAMPLE VOL.	30 (15 $\mu$ L)
FILTER P.	550
BIC. CHEM.	NO
DELAY TIME	7:00
INCUBATE	2:30
BLANK TYPE	NO
% REAGENT VOL.	60 (300 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	mmol/L
UNIT FACTOR	1.000
DECIMAL	2
RBL. LOW	0.000
RBL. HIGH	0.300
RANGE LOW	0.00
RANGE HIGH	7.0
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0.000
NORMAL LOW	2.0
NORMAL HIGH	2.8
SLOPE	1.00
INTERCEPTION	0.00
LINEAR FACTOR	2.65
ENDPOINT LIMIT	0.100
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

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# GAMMA-GLUTAMYLTRANSFERASE (GGT)

Continuous-spectrophotometric  
IFCC

## Instrument: OPERA

### Principle of the method

Gamma-glutamyltransferase ( $\gamma$ -GT) catalyzes the transfer of the  $\gamma$ -glutamyl group from  $\gamma$ -glutamyl-3-carboxy-4-nitroanilide to glycylglycine, liberating 3-carboxy-4-nitroaniline. The catalytic concentration is determined from the rate of 3-carboxy-4-nitroaniline formation.

### Samples

Serum.  
Gamma-glutamyltransferase in serum is stable for 5 days at 2-8 °C.

### Reagent preparation

Working Reagent: Pour the contents of the Reagent B into the Reagent A bottle. Mix gently.  
Stable for 2 months at 2-8 °C.

### Performance characteristics

- Linearity: up to 300 U/L.

## Instrument settings

CHEM. #	(*)
NAME	GGT
IMMUNOASSAY	NO
TYPE	ZERO ORDER
INVERSE	NO
% SAMPLE VOL.	60 (30 $\mu$ L)
FILTER P.	405
BIC. CHEM.	NO
DELAY TIME	0:30
BLANK	NO
% REAGENT VOL.	60 (300 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	U/L
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.150
RBL. HIGH	0.800
RANGE LOW	0.0
RANGE HIGH	300
CAL. FACTOR (**)	1587
REAGENT RATE	0.000
NORMAL LOW	10
NORMAL HIGH	60
SLOPE	1.00
INTERCEPTION	0:00
C1*10E-6	0.00
C2*10E-6	99999
D1*10E-6	5.60
DELTA#	0.010
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay

# GLUCOSE

Enzymatic-spectrophotometric  
GLUCOSE OXIDASE/PEROXIDASE

## Instrument: OPERA

### Principle of the method

Glucose in the sample originates, by means of some coupled reactions, a coloured complex that can be measured by spectrophotometry.

### Samples

Serum, plasma.

Stable for 7 days at 2-8°C.

Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

### Reagent preparation

Reagent is ready to be used.

### Performance characteristics

- Linearity: up to 500 mg/dL.
- Interferences: Hemoglobin (0.3 g/L), bilirubin (15 mg/dL) and ascorbic acid (10 mg/dL) do not interfere. Moderate lipemia does not affect the results.

## Instrument settings

CHEM. #	(*)
NAME	GLU
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	7 (3.5 $\mu$ L)
FILTER P.	500
BIC. CHEM.	NO
DELAY TIME	5:00
BLANK TYPE	NO
% REAGENT VOL.	70 (350 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	Mg/dL
UNIT FACTOR	1.000
DECIMAL	1
RBL. LOW	0.000
RBL. HIGH	0.040
RANGE LOW	0.00
RANGE HIGH	500
CAL. FACTOR	(**)
STANDARD VALUE	(***)
NORMAL LOW	76
NORMAL HIGH	110
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.010

(\*) Data entered by the operator  
(\*\*) CAL. FACTOR is determined by a calibration assay  
(\*\*\*) Assigned value of the standard

# HDL CHOLESTEROL

Precipitation/Enzymatic-spectrophotometric  
PHOSPHOTUNGSTATE/Mg<sup>2+</sup>-CHOLESTEROL OXIDASE/PEROXIDASE

## Instrument: OPERA

### Principle of the method

Very low density lipoproteins (VLDL) and low density lipoproteins (LDL) in the sample precipitate with phosphotungstate and magnesium ions. The supernatant contains high density lipoproteins (HDL). The HDL cholesterol is then spectrophotometrically measured by means of some coupled reactions.

### Samples

Serum or plasma. Stable for 7 days at 2-8°C.

Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

### Precipitation Procedure:

1. Pipette into labelled centrifuge tubes:
 

Sample	0.2 mL
Reagent A	0.5 mL
2. Mix thoroughly and let stand for 10 minutes at room temperature.
3. Centrifuge at a minimum of 4000 r.p.m. for 10 minutes.
4. Carefully collect the supernatant.

### Reagent preparation

Reagent B is ready to be used.

### Performance characteristics

- Linearity: up to 200 mg/dL.
- Interferences: Hemoglobin (1 g/L), bilirubin (10 mg/dL) and acid ascorbic (0.1 mmol/L) interfere.

## Instrument settings

CHEM. #	(*)
NAME	HDL-C
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	34 (17.5 ▀)
FILTER P.	500
BIC. CHEM.	NO
DELAY TIME	3:00
BLANK TYPE	NO
% REAGENT VOL.	60 (300 ▀)
2 <sup>ND</sup> REAGENT	NO
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.040
RANGE LOW	0.00
RANGE HIGH	200
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0.000
NORMAL LOW	30
NORMAL HIGH	70
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.010
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# IRON

Spectrophotometric  
FERROZINE

## Instrument: OPERA

### Principle of the method

Transferrin-bound ferric ions in the sample are released by guanidinium and reduced to ferrous by means of hydroxylamine. Ferrous ions react with ferrozine forming a coloured complex that can be measured by spectrophotometry.

### Samples

Serum or heparinized plasma.  
Stable for 7 days at 2-8°C.

### Reagent preparation

Reagent 1: Use the Reagent A.  
Reagent 2: Use the Reagent B.

### Performance characteristics

- Linearity: up to 1000 µg/dL.
- Interferences: Do not use hemolyzed sera.

### Instrument settings

CHEM. #	(*)
NAME	IRON
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	60 (30 <input checked="" type="checkbox"/> mL)
FILTER P.	550
BIC. CHEM.	NO
DELAY TIME	4:00
BLANK TYPE	DEFAULT
% REAGENT VOL.	60 (300 <input checked="" type="checkbox"/> mL)
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT VOL.	15 (75 <input checked="" type="checkbox"/> mL)
A2 DELAY	4:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	1.000
RANGE LOW	0.00
RANGE HIGH	1000
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0
NORMAL LOW	55
NORMAL HIGH	155
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	1.000
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# LACTATE DEHYDROGENASE (LDH)

Continuous-spectrophotometric  
PYRUVATE

## Instrument: OPERA

### Principle of the method

Lactate dehydrogenase (LD or LDH) catalyzes the reduction of pyruvate by NADH, to form lactate and NAD<sup>+</sup>. The catalytic concentration is determined from the rate of decrease of NADH, measured at 340 nm.

### Samples

Serum or plasma.

Lactate dehydrogenase in serum or plasma is stable for 24 hours at 2-8°C.

Heparin may be used as anticoagulant.

### Reagent preparation

Working Reagent: Pour the contents of the Reagent B into the Reagent A bottle. Mix gently.

Stable for 2 months at 2-8°C.

### Performance characteristics

- Interferences: Hemolysis interferes due to the high lactate dehydrogenase concentration in red cells.
- Linearity: Up to 1500 U/L.

### Instrument settings

CHEM. #	(*)
NAME	LDH
IMMUNOASSAY	NO
TYPE	ZERO ORDER
INVERSE	YES
% SAMPLE VOL.	10 (5 $\mu$ L)
FILTER P.	340
BIC. CHEM.	NO
DEPLETION LIMIT	0.150
DELAY TIME	0:30
BLANK	NO
% REAGENT VOL.	60 (300 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	U/L
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.7
RANGE LOW	0.0
RANGE HIGH	1500
CAL. FACTOR (**)	13833
REAGENT RATE	0.000
NORMAL LOW	207
NORMAL HIGH	414
SLOPE	1.00
INTERCEPTION	0:00
C1*10E-6	0.00
C2*10E-6	99999
D1*10E-6	6.00
DELTA#	0.005
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay

# LDL CHOLESTEROL

Precipitation/Enzymatic-spectrophotometric  
POLIVINYL SULPHATE-CHOLESTEROL OXIDASE/PEROXIDASE

## Instrument: OPERA

### Principle of the method

Low density lipoproteins (LDL) in the sample precipitate with polivinyl sulphate. The supernatant contains low density lipoproteins (LDL). LDL cholesterol concentration is calculated by subtracting cholesterol values in serum from supernatant values after being precipitated. The LDL cholesterol is then spectrophotometrically measured by means of some coupled reactions.

### Samples

Serum. Stable for 24 hours at 2-8°C.

### Sample preparation

#### Precipitation:

- 1.- Pipette into labelled centrifuge tubes: 0.2 mL Sample + 0.1 mL Reagent B
- 2.- Mix thoroughly and let stand for 15 minutes at room temperature
- 3.- Centrifuge at a minimum of 4000 r.p.m. for 15 minutes
- 4.- Carefully collect the supernatant

### Reagent preparation

Reagent is ready to be used.

### Performance characteristics

- Linearity: up to 500 mg/dL.
- Interferences: Hemoglobin (1 g/L), bilirubin (10 mg/dL) and acid ascorbic (0.1 mmol/L) interfere.

## Instrument settings

CHEM. #	(*)
NAME	LDL-C
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	14 (7 $\mu$ L)
FILTER P.	500
BIC. CHEM.	NO
DELAY TIME	3:00
BLANK TYPE	NO
% REAGENT VOL.	70 (350 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	1
RBL. LOW	0.000
RBL. HIGH	0.040
RANGE LOW	0.00
RANGE HIGH	500
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0.000
NORMAL LOW	
NORMAL HIGH	150
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.010
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# LIPASE

Continuous-spectrophotometric

## Instrument: OPERA

### Principle of the method

Lipase catalyzes the hydrolysis of diglyceride to monoglyceride and fatty acid. The catalytic concentration is determined from the rate of quinoneimine formation, measured at 550 nm, by means of the monoglyceride lipase (MGL), glycerol kinase, glycerol phosphate oxidase (GPO) and peroxidase coupled reactions.

### Samples

Serum.

Lipase in serum is stable for 5 days at 2-8°C.

### Reagent preparation

Reagent 1: Reconstitute the contents of a Reagent B vial with 10 mL of Reagent A. Swirl gently. Stable for 28 days at 2-8°C.

Reagent 2: Use the Reagent C.

### Performance characteristics

- Linearity: up to 500 U/L.
- Interferences: Bilirubin (20 mg/dL) and glycerol (100 mg/dL) do not interfere.

### Instrument settings

CHEM. #	(*)
NAME	LIP
IMMUNOASSAY	NO
TYPE	ZERO ORDER
INVERSE	NO
% SAMPLE VOL.	10 (5 $\mu$ L)
FILTER P.	550
BIC. CHEM.	NO
DELAY TIME	2:45
% REAGENT VOL.	50 (250 $\mu$ L)
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	10 (50 $\mu$ L)
A2 DELAY	3:00
UNITS	U/L
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.0
RANGE HIGH	500
CAL. FACTOR (**)	
REAGENT RATE	0.000
NORMAL LOW	7
NORMAL HIGH	59
SLOPE	1.00
INTERCEPTION	0:00
C1*10E-6	0.00
C2*10E-6	99999
D1*10E-6	6.00
DELTA#	0.010
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay

# MAGNESIUM

Spectrophotometric  
CALMAGITE

## Instrument: OPERA

### Principle of the method

Magnesium in the sample reacts with calmagite in alkaline medium forming a coloured complex that can be measured by spectrophotometry. EGTA is included in the reagent to remove calcium interference.

### Samples

Serum, heparinized plasma.

Magnesium in serum or plasma is stable for 10 days at 2-8°C.

Anticoagulants other than heparin should not be used.

### Reagent preparation

Reagent is ready to be used.

### Performance characteristics

- Linearity: up to 4 mg/dL.
- Interferences: Hemoglobin (1.5 g/L), bilirubin (20 mg/dL) and calcium (20 mg/dL) do not interfere.

### Instrument settings

CHEM. #	(*)
NAME	MG
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	6 (3 $\mu$ L)
FILTER P.	500
BIC. CHEM.	NO
DELAY TIME	1:00
BLANK TYPE	NO
% REAGENT VOL.	60 (300 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	1
RBL. LOW	0.280
RBL. HIGH	0.490
RANGE LOW	0.00
RANGE HIGH	4.0
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0.000
NORMAL LOW	1.8
NORMAL HIGH	2.1
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.010
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# PHOSPHORUS

Spectrophotometric  
PHOSPHOMOLYBDATE/UV

## Instrument: OPERA

### Principle of the method

Inorganic phosphorus in the sample reacts with molybdate in acid medium forming a phosphomolybdate complex that can be measured by spectrophotometry.

### Samples

Serum, plasma, urine.

Phosphorus in serum or plasma is stable for 7 days at 2-8°C. EDTA and fluoride may be used as anticoagulants.

### Reagent preparation

Reagent 1: Use the Reagent A.

Reagent 2: Use the Reagent B.

### Performance characteristics

- Linearity: up to 20 mg/dL.
- Interferences: Do not use hemolyzed sera.

### Instrument settings

CHEM. #	(*)
NAME	PHOS
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	8 (4 $\mu$ L)
FILTER P.	340
BIC. CHEM.	NO
DELAY TIME	4:00
BLANK TYPE	NO
% REAGENT VOL.	64 (320 $\mu$ L)
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT VOL.	21 (105 $\mu$ L)
A2 DELAY	2:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	1
RBL. LOW	0.000
RBL. HIGH	0.400
RANGE LOW	0.00
RANGE HIGH	20.0
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT BLANK	0
NORMAL LOW	2.7
NORMAL HIGH	4.5
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.050
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# PROTEIN

Spectrophotometric  
BIURET

## Instrument: OPERA

### Principle of the method

Protein in the sample reacts with copper (II) ion in alkaline medium forming a coloured complex that can be measured by spectrophotometry.

### Samples

Serum, heparinized plasma.

Stable for 8 days at 2-8°C.

Anticoagulants other than heparin should not be used.

### Reagent preparation

Reagent is ready to be used.

### Performance characteristics

- Linearity: up to 150 g/L.
- Interferences: Hemoglobin (0.2 g/L) and bilirubin (15 mg/dL) interfere. Moderate lipemia does not affect the results.

### Instrument settings

CHEM. #	(*)
NAME	PROT
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	14 (7 $\mu$ L)
FILTER P.	550
BIC. CHEM.	NO
DELAY TIME	5:00
BLANK	NO
% REAGENT VOL.	70 (350 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	g/L
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.150
RANGE LOW	0.0
RANGE HIGH	150
CAL. FACTOR	(**)
STANDARD VALUE	(***)
NORMAL LOW	65
NORMAL HIGH	80
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.010
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# PROTEIN (URINE)

Spectrophotometric  
PYROGALLOL RED

## Instrument: OPERA

### Principle of the method

Protein in the sample reacts with pyrogallol red and molybdate in acid medium forming a coloured complex that can be measured by spectrophotometry.

### Samples

Urine, cerebrospinal fluid.  
Stable for 8 days at 2-8°C.

### Reagent preparation

Reagent is ready to be used.

### Performance characteristics

- Linearity: up to 4 g/L.

### Instrument settings

CHEM. #	(*)
NAME	PROT-UR
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	24 (12 $\mu$ L)
FILTER P.	600
BIC. CHEMISTRY	YES
BIC. WAVELENGTH	550
BIC. TYPE	FIXED
BIC. FACTOR	1
DELAY TIME	3:00
BLANK	NO
% REAGENT VOL.	60 (300 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.150
RANGE LOW	0.0
RANGE HIGH	200
CAL. FACTOR	(**)
STANDARD VALUE	(***)
NORMAL LOW	3.0
NORMAL HIGH	14.0
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.50
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# TRIGLYCERIDES

Enzymatic-spectrophotometric  
GLYCEROL PHOSPHATE OXIDASE/PEROXIDASE

## Instrument: OPERA

### Principle of the method

Triglycerides in the sample originates, by means of some coupled reactions, a coloured complex that can be measured by spectrophotometry.

### Samples

Serum or plasma.

Stable for 5 days at 2-8°C.

Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

### Reagent preparation

Reagent is ready to be used.

### Performance characteristics

- Linearity: up to 600 mg/dL.
- Interferences: Hemoglobin (3 g/L), bilirubin (0.25 mmol/L) and ascorbic acid (0.3 mmol/L) interfere. Lipemia does not affect results.

### Instrument settings

CHEM. #	(*)
NAME	TRIG
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	6 (3 $\mu$ L)
FILTER P.	500
BIC. CHEM.	NO
DELAY TIME	4:00
BLANK TYPE	NO
% REAGENT VOL.	60 (300 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.050
RANGE LOW	0.00
RANGE HIGH	600
CAL. FACTOR	(**)
STANDARD VALUE	(***)
NORMAL LOW	60
NORMAL HIGH	150
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.020

(\*) Data entered by the operator  
(\*\*) CAL. FACTOR is determined by a calibration assay  
(\*\*\*) Assigned value of the standard

# UREA/BUN

Enzymatic-spectrophotometric  
ULTRAVIOLET

## Instrument: OPERA

### Principle of the method

Urea in the sample consumes, by means of some coupled reactions, NADH that can be measured by spectrophotometry.

### Samples

Serum, plasma, urine.  
Stable for 7 days at 2-8°C.  
Heparin is recommended as anticoagulant.

### Reagent preparation

Working Reagent: Transfer the contents of one Reagent B vial into a Reagent A bottle. Mix thoroughly.  
Stable for 2 months at 2-8°C.

### Performance characteristics

- Linearity: up to 300 mg/dL.
- Interferences: Ammonium salts of the anticoagulants interfere.

### Instrument settings

CHEM. #	(*)
NAME	UREA UV
IMMUNOASSAY	NO
TYPE	FIRST ORDER
INVERSE	YES
% SAMPLE VOL.	5 (2.5 $\mu$ L)
FILTER P.	340
BIC. CHEM.	NO
DELAY TIME	0:30
INCUBATE	1:00
% REAGENT VOL.	75 (375 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.600
RANGE LOW	0.00
RANGE HIGH	300
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0
NORMAL LOW	10
NORMAL HIGH	50
SLOPE	1.00
INTERCEPTION	0.00
LINEAR FACTOR	1.0
FIRST LIMIT	0.040
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# URIC ACID

Enzymatic-spectrophotometric  
URICASE/PEROXIDASE

## Instrument: OPERA

### Principle of the method

Uric acid in the sample originates, by means of some coupled reactions, a coloured complex that can be measured by spectrophotometry.

### Samples

Serum, plasma, urine.

Uric acid in serum or plasma is stable for 7 days at 2-8°C.

Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

### Reagent preparation

Reagent is ready to be used.

### Performance characteristics

- Linearity: up to 25 mg/dL.
- Interferences: Hemoglobin (1 g/L), bilirubin (15 mg/dL) and ascorbic acid (0.3 mmol/L) do not interfere. Lipemia may affect the results.

### Instrument settings

CHEM. #	(*)
NAME	URIC
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	18 (9 $\mu$ L)
FILTER P.	500
BIC. CHEM.	NO
DELAY TIME	3:00
BLANK TYPE	NO
% REAGENT VOL.	70 (350 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	1
RBL. LOW	0.000
RBL. HIGH	0.040
RANGE LOW	0.00
RANGE HIGH	25.0
CAL. FACTOR	(**)
STANDARD VALUE	(***)
NORMAL LOW	2.40
NORMAL HIGH	7.00
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.010

(\*) Data entered by the operator  
(\*\*) CAL. FACTOR is determined by a calibration assay  
(\*\*\*) Assigned value of the standard

# APOLIPOPROTEIN A-1 (Apo A-1)

Turbidimetry

Instrument: **OPERA**

### Principle of the method

Apolipoprotein A-1 in the sample precipitates in the presence of anti-human apolipoprotein A-1 antibodies. The light scattering of the antigen-antibody complexes is proportional to the apolipoprotein A-1 concentration and can be measured by turbidimetry.

### Samples

Serum or plasma collected by standard procedures. Use heparin or EDTA as anticoagulants. Do not freeze the samples.  
Stable for 7 days at 2-8°C.




### Reagent preparation

Reagent 1: Use the Reagent A.  
Reagent 2: Use the Reagent B.

### Performance characteristics

- Interferences: bilirubin (20 mg/dL) and rheumatoid factors (300 UI/mL) do not interfere. Hemoglobin (10 g/L) and lipemia (triglycerides 2.5 g/L) may interfere. Other drugs and substances may interfere.

### Instrument settings

CHEM. #	(*)
NAME	APO A1
IMMUNOASSAY	YES
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	5 (2.5  )
FILTER P.	340
BIC. CHEMISTRY	NO
DELAY TIME	5:00
% REAGENT VOL.	60 (300  )
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	15 (75  )
A2 DELAY	2:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	*
NORMAL LOW	94
NORMAL HIGH	178
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
IA TYPE	SIMPLE CUBIC
N° OF STANDARDS	6
N° OF ASPIRATIONS	1
STANDARD 1-6	***
%PRECISION /DEVIATION LIMIT 1	99
%PRECISION /DEVIATION LIMIT 2	15
%PRECISION /DEVIATION LIMIT 3	10
%PRECISION /DEVIATION LIMIT 4	10
%PRECISION /DEVIATION LIMIT 5	10
%PRECISION /DEVIATION LIMIT 6	10
R EXP (10) (50) (90)	0.0
% A DEV (10) (50) (90)	99
RSS LIMIT	9999.9
	(*) Data entered by the operator
	(***) Assigned value of the standards

# APOLIPOPROTEIN B (Apo B)

Turbidimetry

Instrument: **OPERA**

### Principle of the method

Apolipoprotein B in the sample precipitates in the presence of anti-human apolipoprotein B antibodies. The light scattering of the antigen-antibody complexes is proportional to the apolipoprotein B concentration and can be measured by turbidimetry.

### Samples

Serum or plasma collected by standard procedures. Use heparin or EDTA as anticoagulants. Do not freeze the samples.  
Stable for 7 days at 2-8°C.




### Reagent preparation

Reagent 1: Use the Reagent A.  
Reagent 2: Use the Reagent B.

### Performance characteristics

- Interferences: bilirubin (20 mg/dL) and rheumatoid factors (300 UI/mL) do not interfere. Hemoglobin (10 g/L) and lipemia (triglycerides 5 g/L) may interfere. Other drugs and substances may interfere.

### Instrument settings

CHEM. #	(*)
NAME	APO B
IMMUNOASSAY	YES
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	7 (3.5  )
FILTER P.	340
BIC. CHEMISTRY	NO
DELAY TIME	5:00
% REAGENT VOL.	56 (280  )
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	14 (70  )
A2 DELAY	2:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	*
NORMAL LOW	63
NORMAL HIGH	133
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
IA TYPE	SIMPLE CUBIC
N° OF STANDARDS	6
N° OF ASPIRATIONS	1
STANDARD 1-6	***
%PRECISION /DEVIATION LIMIT 1	99
%PRECISION /DEVIATION LIMIT 2	15
%PRECISION /DEVIATION LIMIT 3	10
%PRECISION /DEVIATION LIMIT 4	10
%PRECISION /DEVIATION LIMIT 5	10
%PRECISION /DEVIATION LIMIT 6	10
R EXP (10) (50) (90)	0.0
% A DEV (10) (50) (90)	99
RSS LIMIT	9999.9
	(*) Data entered by the operator
	(***) Assigned value of the standards

# ANTI-STREPTOLYSIN O (ASO)

Turbidimetry  
LATEX

## Instrument: OPERA

### Principle of the method

Anti-streptolysin O (ASO) causes agglutination of the latex particles coated with streptolysin O. The agglutination of the particles is proportional to the ASO concentration and can be measured by turbidimetry.

### Samples

Serum. Stable for 7 days at 2-8°C.

Hemolyzed or lipemic samples are not suitable for testing.

### Reagent preparation

Reagent 1: Use the Diluent.

Reagent 2: Use the Latex.

### Performance characteristics

- Linearity: up to 800 IU/mL.

## Instrument settings

CHEM. #	(*)
NAME	ASO
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	7 (3.5 $\mu$ L)
FILTER P.	550
BIC. CHEMISTRY	NO
DELAY TIME	2:00
% REAGENT VOL.	63 (315 $\mu$ L)
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	7 (35 $\mu$ L)
A2 DELAY	2:00
UNITS	IU/mL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	600
CAL. FACTOR	(**)
STANDARD VALUE	(***)
NORMAL LOW	0
NORMAL HIGH	200
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# COMPLEMENT COMPONENT C3

Turbidimetry

## Instrument: OPERA

### Principle of the method

Complement component C3 precipitates in the presence of anti-human C3 antibodies. The originated turbidity is proportional to the C3 concentration and can be measured by turbidimetry.

### Samples

Serum or plasma treated with heparin or EDTA. Stable for 7 days at 2-8°C. Hemolyzed or lipemic samples are not suitable for testing.




### Reagent preparation

Reagent 1: Use the Reagent A.  
Reagent 2: Use the Reagent B.

### Performance characteristics

- Due to the zone effect, falsely low values will be obtained when C3 is present in the sample at a concentration higher than 600 mg/dL.

### Instrument settings

CHEM. #	(*)
NAME	C3
IMMUNOASSAY	YES
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	7 (3.5  )
FILTER P.	340
BIC. CHEMISTRY	NO
DELAY TIME	5:00
% REAGENT VOL.	56 (280  )
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	14 (70  )
A2 DELAY	2:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	600
NORMAL LOW	90
NORMAL HIGH	180
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
IA TYPE	SIMPLE CUBIC
N° OF STANDARDS	6
N° OF ASPIRATIONS	1
STANDARD 1-6	***
%PRECISION /DEVIATION LIMIT 1	99
%PRECISION /DEVIATION LIMIT 2	15
%PRECISION /DEVIATION LIMIT 3	10
%PRECISION /DEVIATION LIMIT 4	10
%PRECISION /DEVIATION LIMIT 5	10
%PRECISION /DEVIATION LIMIT 6	10
R EXP (10) (50) (90)	0.0
% A DEV (10) (50) (90)	99
RSS LIMIT	9999.9

(\*) Data entered by the operator  
(\*\*) Assigned value of the standards

# COMPLEMENT COMPONENT C4

Turbidimetry

## Instrument: OPERA

### Principle of the method

Complement component C4 precipitates in the presence of anti-human C4 antibodies. The originated turbidity is proportional to the C4 concentration and can be measured by turbidimetry.

### Samples

Serum or plasma treated with heparin or EDTA. Stable for 7 days at 2-8°C. Hemolyzed or lipemic samples are not suitable for testing.

### Reagent preparation

Reagent 1: Use the Reagent A.  
Reagent 2: Use the Reagent B.

### Performance characteristics

- Due to the zone effect, falsely low values will be obtained when C4 is present in the sample at a concentration higher than 150 mg/dL.

### Instrument settings

CHEM. #	(*)
NAME	C4
IMMUNOASSAY	YES
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	21 (10.5 $\mu$ l)
FILTER P.	340
BIC. CHEMISTRY	NO
DELAY TIME	5:00
% REAGENT VOL.	56 (280 $\mu$ l)
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	14 (70 $\mu$ l)
A2 DELAY	2:00
UNITS	Mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	150
NORMAL LOW	10
NORMAL HIGH	40
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
IA TYPE	SIMPLE CUBIC
N° OF STANDARDS	6
N° OF ASPIRATIONS	1
STANDARD 1-6	***
%PRECISION /DEVIATION LIMIT 1	99
%PRECISION /DEVIATION LIMIT 2	15
%PRECISION /DEVIATION LIMIT 3	10
%PRECISION /DEVIATION LIMIT 4	10
%PRECISION /DEVIATION LIMIT 5	10
%PRECISION /DEVIATION LIMIT 6	10
R EXP (10) (50) (90)	0.0
% A DEV (10) (50) (90)	99
RSS LIMIT	9999.9

(\*) Data entered by the operator  
(\*\*) Assigned value of the standards

# C-REACTIVE PROTEIN (CRP)

Turbidimetry  
LATEX

## Instrument: OPERA

### Principle of the method

Serum C-reactive protein (CRP) causes agglutination of the latex particles coated with anti-human C-reactive protein. The agglutination of the latex particles is proportional to the CRP concentration and can be measured by turbidimetry.

### Samples

Serum. Stable for 7 days at 2-8°C.  
Hemolyzed or lipemic samples are not suitable for testing.

### Reagent preparation

Reagent 1: Use the Diluent.  
Reagent 2: Use the Latex.

### Performance characteristics

- Linearity: up to 150 mg/L.
- Interferences: Rheumatoid factors, up to 200 IU/mL do not interfere.

### Instrument settings

CHEM. #	(*)
NAME	CRP
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	4 (2 $\mu$ L)
FILTER P.	550
BIC. CHEMISTRY	NO
DELAY TIME	2:00
% REAGENT VOL.	72 (360 $\mu$ L)
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	8 (40 $\mu$ L)
A2 DELAY	2:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	150
CAL. FACTOR	(**)
STANDARD VALUE	(***)
NORMAL LOW	0.0
NORMAL HIGH	6.0
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# FERRITIN

Turbidimetry  
LATEX

## Instrument: OPERA

### Principle of the method

Serum ferritin causes agglutination of the latex particles coated with anti-human ferritin antibodies. The agglutination of the latex particles is proportional to the ferritin concentration and can be measured by turbidimetry.

### Samples

Serum. Stable for 7 days at 2-8°C.

Hemolyzed or lipemic samples are not suitable for testing.

### Reagent preparation

Working Reagent: Mix nine volumes of Diluent with one volume of Latex.

Stable for 1 day at 2-8°C.

Shake the latex vial gently before using.

### Performance characteristics

- Linearity: up to 300 µg/L.
- The zone effect will cause to obtain falsely low values when ferritin is present in the sample at a concentration higher than 9 mg/L.
- Interferences: Rheumatoid factors, up to 1000 IU/mL do not interfere.

### Instrument settings

CHEM. #	(*)
NAME	FERRITIN
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	60 (30 <input checked="" type="checkbox"/> L)
FILTER P.	550
BIC. CHEMISTRY	NO
DELAY TIME	8:00
% REAGENT VOL.	60 (300 <input checked="" type="checkbox"/> L)
2 <sup>ND</sup> REAGENT	NO
UNITS	µg/L
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	1.200
RANGE LOW	0.00
RANGE HIGH	300
CAL. FACTOR	(**)
STANDARD VALUE	(***)
NORMAL LOW	20
NORMAL HIGH	220
SLOPE	1.000
INTERCEPTION	0.000
ENDPOINT LIMIT	0.150
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# IMMUNOGLOBULIN A

Turbidimetry

## Instrument: OPERA

### Principle of the method

Immunoglobulin A precipitates in the presence of anti-human Immunoglobulin A antibodies. The originated turbidity is proportional to the Immunoglobulin A concentration and can be measured by turbidimetry.

### Samples

Serum or plasma treated with heparin or EDTA.

Stable 7 days at 2-8 °C.

Hemolyzed or lipemic samples are not suitable for testing.

### Reagent preparation




Reagent 1: Use the Reagent A bottle.

Reagent 2: Use the Reagent B bottle.

### Performance characteristics

- The measurement interval depends on concentration of the highest standard.
- Due to the zone effect, falsely low values will be obtained when IgA is present in the sample at a concentration higher than 1300 mg/dL.

### Instrument settings

CHEM. #	(*)
NAME	IGA
IMMUNOASSAY	YES
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	7 (3.5  )
FILTER P.	600
BIC. CHEMISTRY	NO
DELAY TIME	5:00
% REAGENT VOL.	56 (280  )
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	14 (70  )
A2 DELAY	2:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	1300
NORMAL LOW	70
NORMAL HIGH	400
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
IA TYPE	SIMPLE CUBIC
N° OF STANDARDS	6
N° OF ASPIRATIONS	1
STANDARD 1-6	***
%PRECISION /DEVIATION LIMIT 1	99
%PRECISION /DEVIATION LIMIT 2	15
%PRECISION /DEVIATION LIMIT 3	10
%PRECISION /DEVIATION LIMIT 4	10
%PRECISION /DEVIATION LIMIT 5	10
%PRECISION /DEVIATION LIMIT 6	10
R EXP (10) (50) (90)	0.0
% A DEV (10) (50) (90)	99
RSS LIMIT	9999.9
	(*) Data entered by the operator
	(***) Assigned value of the standards

# IMMUNOGLOBULIN G

Turbidimetry

## Instrument: OPERA

### Principle of the method

Immunoglobulin G precipitates in the presence of anti-human Immunoglobulin G antibodies. The originated turbidity is proportional to the Immunoglobulin G concentration and can be measured by turbidimetry.

### Samples

Serum or plasma treated with heparin or EDTA.

Stable 7 days at 2-8 °C.

Hemolyzed or lipemic samples are not suitable for testing.

### Reagent preparation




Reagent 1: use the Reagent A.

Reagent 2: use the Reagent B.

### Performance characteristics

- The measurement interval depends on concentration of the highest standard.
- Due to the zone effect, falsely low values will be obtained when IgG is present in the sample at a concentration higher than 8000 mg/dL.

### Instrument settings

CHEM. #	(*)
NAME	IGG
IMMUNOASSAY	YES
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	5 (2.5  )
FILTER P.	600
BIC. CHEMISTRY	NO
DELAY TIME	5:00
% REAGENT VOL.	60 (300  )
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	15 (75  )
A2 DELAY	2:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	8000
NORMAL LOW	700
NORMAL HIGH	1600
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
IA TYPE	SIMPLE CUBIC
N° OF STANDARDS	6
N° OF ASPIRATIONS	1
STANDARD 1-6	***
%PRECISION /DEVIATION LIMIT 1	99
%PRECISION /DEVIATION LIMIT 2	15
%PRECISION /DEVIATION LIMIT 3	10
%PRECISION /DEVIATION LIMIT 4	10
%PRECISION /DEVIATION LIMIT 5	10
%PRECISION /DEVIATION LIMIT 6	10
R EXP (10) (50) (90)	0.0
% A DEV (10) (50) (90)	99
RSS LIMIT	9999.9
	(*) Data entered by the operator
	(***) Assigned value of the standards

# IMMUNOGLOBULIN M

Turbidimetry

## Instrument: OPERA

### Principle of the method

Immunoglobulin M precipitates in the presence of anti-human Immunoglobulin M antibodies. The originated turbidity is proportional to the Immunoglobulin M concentration and can be measured by turbidimetry.

### Samples

Serum or plasma treated with heparin or EDTA.

Stable 7 days at 2-8 °C.

Hemolyzed or lipemic samples are not suitable for testing.

### Reagent preparation




Reagent 1: use the Reagent A.

Reagent 2: use the Reagent B.

### Performance characteristics

- The measurement interval depends on concentration of the highest standard.
- Due to the zone effect, falsely low values will be obtained when IgM is present in the sample at a concentration higher than 600 mg/dL.

### Instrument settings

CHEM. #	(*)
NAME	IGM
IMMUNOASSAY	YES
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	14 (7  )
FILTER P.	340
BIC. CHEMISTRY	NO
DELAY TIME	5:00
% REAGENT VOL.	56 (280  )
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	14 (70  )
A2 DELAY	2:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	600
NORMAL LOW	40
NORMAL HIGH	230
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
IA TYPE	SIMPLE CUBIC
N° OF STANDARDS	6
N° OF ASPIRATIONS	1
STANDARD 1-6	***
%PRECISION /DEVIATION LIMIT 1	99
%PRECISION /DEVIATION LIMIT 2	15
%PRECISION /DEVIATION LIMIT 3	10
%PRECISION /DEVIATION LIMIT 4	10
%PRECISION /DEVIATION LIMIT 5	10
%PRECISION /DEVIATION LIMIT 6	10
R EXP (10) (50) (90)	0.0
% A DEV (10) (50) (90)	99
RSS LIMIT	9999.9
	(*) Data entered by the operator
	(**) Assigned value of the standards

# ALBUMIN (URINE)

Turbidimetry  
LATEX

## Instrument: OPERA

### Principle of the method

Albumin in the urine sample causes agglutination of the latex particles coated with anti-human albumin. The agglutination of the particles is proportional to the albumin concentration and can be measured by turbidimetry.

### Samples

Urine. Stable for 7 days at 2-8°C.

Urine should be centrifugated before analysis.

### Reagent preparation

Working Reagent: Pour the contents of a Latex vial into a Diluent bottle. Mix thoroughly.

Stable for 8 hours at 2-8°C.

### Performance characteristics

- Linearity: up to 130 mg/L.
- The zone effect will cause to obtain falsely low values when albumin is present in the sample at a concentration higher than 1000 mg/L.

### Instrument settings

CHEM. #	(*)
NAME	ALB-U
IMMUNOASSAY	NO
TYPE	FIRST ORDER
INVERSE	NO
% SAMPLE VOL.	5 (2.5 $\mu$ L)
FILTER P.	550
DELAY TIME	2:00
% REAGENT VOL.	70 (350 $\mu$ L)
2 <sup>ND</sup> REAGENT	NO
UNITS	mg/L
UNIT FACTOR	1.000
DECIMAL	1
RBL. LOW	0.000
RBL. HIGH	1.200
RANGE LOW	0.00
RANGE HIGH	130
CAL. FACTOR	(**)
STANDARD VALUE	(***)
REAGENT RATE	0
NORMAL LOW	0.0
NORMAL HIGH	15.0
SLOPE	1.00
INTERCEPTION	0.00
LINEAR FACTOR	2.65
FIRST LIMIT	0.50
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# RHEUMATOID FACTORS (RF)

Turbidimetry  
LATEX

## Linear calibration

### Instrument: OPERA

#### Principle of the method

Rheumatoid factors (RF) causes agglutination of the latex particles coated with human gamma-globulin. The agglutination of the latex particles is proportional to the RF concentration and can be measured by turbidimetry.

#### Samples

Serum. Stable for 7 days at 2-8°C.

Hemolyzed or lipemic samples are not suitable for testing.

#### Reagent preparation

Reagent 1: Use the Diluent.

Reagent 2: Use the Latex.

#### Performance characteristics

- Linearity: up to 120 IU/mL.
- This method has not zone effect up to 800 IU/mL.

### Instrument settings

CHEM. #	(*)
NAME	RF
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	5 (2.5 $\mu$ L)
FILTER P.	600
BIC. CHEMISTRY	NO
DELAY TIME	2:00
% REAGENT VOL.	64 (320 $\mu$ L)
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	7 (35 $\mu$ L)
A2 DELAY	2:00
UNITS	IU/mL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	120
CAL. FACTOR	(**)
STANDARD VALUE	(***)
NORMAL LOW	0
NORMAL HIGH	20
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
	(*) Data entered by the operator
	(**) CAL. FACTOR is determined by a calibration assay
	(***) Assigned value of the standard

# RHEUMATOID FACTORS (RF)

Turbidimetry  
LATEX

## Instrument: OPERA

### Principle of the method

Rheumatoid factors (RF) causes agglutination of the latex particles coated with human gamma-globulin. The agglutination of the latex particles is proportional to the RF concentration and can be measured by turbidimetry.

### Samples

Serum. Stable for 7 days at 2-8°C.

Hemolyzed or lipemic samples are not suitable for testing.

### Reagent preparation

Reagent 1: Use the Diluent.

Reagent 2: Use the Latex.

### Performance characteristics

- Linearity: up to 160 IU/mL.
- This method has not zone effect up to 800 IU/mL.

### Instrument settings

CHEM. #	(*)
NAME	RF
IMMUNOASSAY	YES
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	5 (2.5 $\mu$ L)
FILTER P.	600
BIC. CHEMISTRY	NO
DELAY TIME	2:00
% REAGENT VOL.	64 (320 $\mu$ L)
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	7 (35 $\mu$ L)
A2 DELAY	2:00
UNITS	IU/mL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	160
NORMAL LOW	0
NORMAL HIGH	20
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
IA TYPE	LINEAR LOG-LOGIT
N° OF STANDARDS	6
N° OF ASPIRATIONS	1
STANDARD 1-6	***
%PRECISION /DEVIATION LIMIT 1	99
%PRECISION /DEVIATION LIMIT 2	15
%PRECISION /DEVIATION LIMIT 3	10
%PRECISION /DEVIATION LIMIT 4	10
%PRECISION /DEVIATION LIMIT 5	10
%PRECISION /DEVIATION LIMIT 6	10
R EXP (10) (50) (90)	0.0
% A DEV (10) (50) (90)	99
RSS LIMIT	9999.9

(\*) Data entered by the operator  
(\*\*\*) Assigned value of the standards

# TRANSFERRIN

Turbidimetry

## Instrument: OPERA

### Principle of the method

Transferrin precipitates in the presence of anti-human transferrin antibodies. The originated turbidity is proportional to the transferrin concentration and can be measured by turbidimetry.

### Samples

Serum or plasma treated with heparin or EDTA.  
Stable for 7 days at 2-8°C.




### Reagent preparation

Reagent 1: Use the Reagent A.  
Reagent 2: Use the Reagent B.

### Performance characteristics

- Interferences: Hemoglobin (10 g/L), bilirubin (20 mg/dL) and Rheumatoid factors (300 UI/mL) do not interfere. Lipemia does not affect the results (5 g/L).

### Instrument settings

CHEM. #	(*)
NAME	TRANS
IMMUNOASSAY	YES
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	5 (2.5  )
FILTER P.	340
BIC. CHEMISTRY	NO
DELAY TIME	5:00
% REAGENT VOL.	60 (300  )
2 <sup>ND</sup> REAGENT	YES
% 2 <sup>ND</sup> REAGENT	15 (75  )
A2 DELAY	2:00
UNITS	mg/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.00
RANGE HIGH	*
NORMAL LOW	200
NORMAL HIGH	360
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
IA TYPE	SIMPLE CUBIC
N° OF STANDARDS	6
N° OF ASPIRATIONS	1
STANDARD 1-6	***
%PRECISION /DEVIATION LIMIT 1	99
%PRECISION /DEVIATION LIMIT 2	15
%PRECISION /DEVIATION LIMIT 3	10
%PRECISION /DEVIATION LIMIT 4	10
%PRECISION /DEVIATION LIMIT 5	10
%PRECISION /DEVIATION LIMIT 6	10
R EXP (10) (50) (90)	0.0
% A DEV (10) (50) (90)	99
RSS LIMIT	9999.9
	(*) Data entered by the operator
	(**) Assigned value of the standards