BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

UREA Colorimetric Method

Reagent for quantitative determination of urea in human serum and plasma or urines.

REF 80221	**R1** 1 x 125 mL	**R2** 1 x 1.25 mL	**R3** 1 x 31 mL	**R4** 1 x 10 mL
REF 80321	**R1** 1 x 500 mL	**R2** 1 x 5 mL	**R3** 1 x 125 mL	**R4** 1 x 10 mL

TECHNICAL SUPPORT AND ORDERS
Tel : (33) 03 23 25 15 50
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CE

IVD IN VITRO DIAGNOSTIC USE

CLINICAL SIGNIFICANCE (1) (5)

More than 90% of urea is excreted through the kidneys in urines. Measurement of the plasma or serum urea concentration is widely regarded as a test of renal function. However, a number of nonrenal factors also influence the circulating urea concentration: Urea increased level occurs when proteins catabolism is accelerated, burns, stress, myocardial infarction... Urea is decreased in acute liver destruction and is accompanied with increased ammonium level. Urea level is generally studied in conjunction with creatinine level (urea/creatinine ratio) to refine post-renal or pre-renal diagnosis.

PRINCIPLE (4)

Enzymatic and colorimetric method based on the specific action of urease which hydrolyses urea in ammonium ions and carbon dioxide. Ammonium ions then form with chloride and salicylate a blue-green complex. This coloration, proportional to urea concentration in the specimen, is measured at 600 nm.

REAGENTS COMPOSITION

Vial R1 **SALICYLATE**

Salicylate	31	mmol/L
Nitroprussiate	1.67	mmol/L

Vial R2 **UREASE**

Urease	≥ 15	KUI/L

Vial R3 **BASE**

Sodium hypochlorite	7	mmol/L
Sodium hydroxide	62	mmol/L

Before dilution: Xi, R36/38, Irritating to eyes and skin
S24-25-26-28: Avoid contact with skin and eyes. After contact with skin, rinse immediatly with plenty of water. After contact with eyes, rinse immediatly with plenty of water and seek medical advice
Once diluted: None

Vial R4 **STANDARD** Urea 40 mg/dL (6.66 mmol/L)

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Verify the integrity of the contents before use.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

REAGENTS PREPARATION

Add contents of vial R2 (Urease) into vial R1 (Salicylate). Mix gently by inversion.

Alkaline (vial R3):

Procedure n°1 and n°2 (manual): Dilute (1 + 3) with demineralised water

Procedure n°3 (manual or automatic): Ready to use

Standard (vial R4): transfer the requested quantity, recap and store at 2-8°C.

STABILITY AND STORAGE

Store at 2-8°C, well recap in the original vial and away from light.

- Unopened, reagents are stable until expiry date stated on the label when stored and used as described in the insert.
- Once reconstituted, working reagent (R1+R2) is stable for 1 month when free from contamination.
- Once opened, Base (vial R3) diluted ¼ is stable for 3 months when free from contamination.
- Once opened, the contents of vial R4 is stable for at least 3 months when free from contamination.

Discard any reagent if cloudy or if absorbance of blank against water at 600 nm > 0.100.

Don't use working reagent or diluted contents of vial R3 after expiry date stated on the label of the kit.

SPECIMEN COLLECTION AND HANDLING (2)

Unhemolysed serum or heparinised plasma. Avoid fluoride or ammonium as anticoagulant which interfere with the assay.

Urea is stable in serum or plasma for:

- 24 h at room temperature.
- several days at 2-8°C.
- at least 2-3 months frozen.

24h Urine: diluted (1+19) with demineralised water before assay.

Urea is stable in urines for:

- 4 days at 2-8°C.

Add antibacterial agent as Thymol to improve the stability.

INTERFERENCES (3)

No interference of assayed substances (ascorbic acid, bilirubin, haemoglobin, triglycerides) with the test.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Normal and pathological control sera

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | Σ sufficient for | → dilute with

CALIBRATION

- Standard enclosed in the kit (vial R4) or BIOLABO Multicalibrator REF 95015 traceable to SRM 909b.
- Or any calibrator traceable to a reference method or material.

The calibration frequency depends on proper instrument functions and on the preservation of reagent.

It is recommended to calibrate in the following cases :

1. When changing batch of reagent.
2. After maintenance operations on the instrument.
3. If control values are out of range, even after using a new vial of fresh control serum.

QUALITY CONTROL

- BIOLABO EXATROL-N Level I REF 95010.
- BIOLABO EXATROL-P Level II REF 95011.
- Other assayed control sera referring to the same method.
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Repeat the test with the same control.
2. If control is still out of range, prepare a fresh control and repeat the test.
3. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
4. If control is still out of range, calibrate with a new vial of reagent.
5. If control is still out of range, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (2)

In serum and plasma	mg/dL	[mmol/L]
In cord	45-86	[7.5-14.3]
Premature	6-54	[1.1-8.9]
< 1 year	9-41	[1.4-6.8]
Children	11-39	[1.8-6.4]
18-60 years	13-43	[2.1-7.1]
60-90 years	17-49	[2.9-8.2]
> 90 years	21-66	[3.6-11.1]
In urines	26-43 g/24 h	[0.43-0.71 mol/24 h]

To calculate blood urea nitrogen (BUN): multiply the value of urea (mg/dL) by 0.467.

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCE CHARACTERISTICS (Procedure n°1)

Within run N = 20	*Normal level*	*High level*
Mean mg/dL	40	141.6
S.D. mg/dL	0.76	1.66
C.V. %	1.89	1.17

Between run N = 20	*Normal level*	*High level*
Mean mg/dL	35	111
S.D. mg/dL	1.58	3.44
C.V. %	4.5	3.1

Detection limit: approximately 10 mg/dL.

Comparison with commercially available reagent: y = 0.9816 + 0.87

r = 0.9961

	Sensitivity for 100 mg/dL at 600 nm
Procedure n°1	Approx. 0.400 abs
Procedure n°2	Approx. 0.800 abs
Procedure n°3	Approx. 0.700 abs

Note: Sensitivity is higher at upper wavelength and lower at inferior wavelength.

LINEARITY

Procedure n°1 and n°3:
The reaction is linear up to 250 mg/dL (41.7 mmol/L).
Procedure n°2: The reaction is linear up to 125 mg/dL (20.9 mmol/L).
Above, dilute the specimen with saline solution and reassay taking into account dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

MANUAL PROCEDURE

Let stand reagents and specimens at room temperature.

Procedure n°1

Pipette into test tubes	Blank	Standard	Assay
Working reagent (R1+R2)	1 mL	1 mL	1 mL
Demineralised water	5 µL		
Standard		5 µL	
Specimen (Note 1)			5 µL
Mix and wait for 4 minutes at room temperature or 2 minutes at 37°C			
Base (vial R3) diluted ¼	1 mL	1 mL	1 mL
Mix. Let stands for 8 minutes at room temperature or 5 minutes at 37°C. Read absorbance at 600 nm (590-610) against blank (Note 3). Reaction coloration is stable for 2 hours.			

Procedure n°2

Pipette into test tubes	Blank	Standard	Assay
Working reagent (R1+R2)	1 mL	1 mL	1 mL
Demineralised water	10 µL		
Standard		10 µL	
Specimen (Note 1)			10 µL
Mix and wait for 4 minutes at room temperature or 2 minutes at 37°C			
Base (vial R3) diluted ¼	1 mL	1 mL	1 mL
Mix. Let stands for 8 minutes at room temperature or 5 minutes at 37°C. Read absorbance at 600 nm (590-610) against blank (Note 3). Reaction coloration is stable for 2 hours.			

Procédure n°3 (alcalin PUR)

Pipette into test tubes	Blanc	Etalon	Dosage
Working reagent (R1+R2)	1 mL	1 mL	1 mL
Demineralised water	5 µL		
Standard		5 µL	
Specimen (Note 1)			5 µL
Mix and wait for 4 minutes at room temperature or 2 minutes at 37°C			
Base (vial R3) PUR	250 µL	250 µL	250 µL
Mix. Let stands for 8 minutes at room temperature or 5 minutes at 37°C. Read absorbance at 600 nm (590-610) against blank (Note 3). Reaction coloration is stable for 2 hours.			

1. Serum, plasma or urines diluted (1+19) with demineralised water.
2. Specific procedures are available upon request for automated instruments. Please contact BIOLABO technical support.
3. The test may be performed **at 578 nm**. In this case, Procedure n°2 is linear up to 300 mg/dL.

CALCULATION

Calculate the result as follows:

Serum and plasma:

$$\text{Result} = \frac{\text{Abs (Assay)}}{\text{Abs (Standard)}} \times \text{Standard concentration}$$

Urines diluted (1+19):

Multiply the result by 20 (dilution factor).

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 1239-1241.*

(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 1096-1099.*

(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1990) p. 3-599 to 3-609*

(4) *SEARCY R.L., REARDON J.E., FOREMAN J.A., Amer. J. Méd. Techn. 1967, 33, 15-20.*

(5) *Bernard S. Bioch. clin. Diagnostics médicaux chirurgicaux 2ème éd. p.143-144. Ed. Maloine PARIS (1989).*

(4) *SRM: Standard Reference Material®*

REPUBLIQUE FRANCAISE

CCI PARIS ILE-DE-FRANCE

Direction Générale Adjointe - Services aux Entreprises et Développement International
Direction des réseaux et partenariats internationaux
Service CLV

Certificat de Libre Vente pour l'exportation vers les pays non membres de l'Union Européenne

Free sale certificate for exportation to the non-EC Member States

dispositifs médicaux de diagnostic in vitro relevant de la directive n°98/79/CE
in vitro diagnostic medical devices covered by Directive 98/79/EC

PARTIE A COMPLETER PAR LE DEMANDEUR
Section to be completed by the applicant

Catégorie(s) du(des) dispositif(s) : : Réactifs et instruments de laboratoires pour la Biologie Médicale

Device(s) category: Reagents § Instruments for Medical Biology

Nombre de page en annexe : 5
Page in annex : 5

La désignation du(des) dispositif(s) apparaît sur la déclaration(s) CE de conformité du fabricant ou du mandataire
The name of the device(s) appears on the EC declaration(s) of conformity of the manufacturer or the authorized representative

Classification du(des) dispositif(s) :
Classification of the device(s) :

☐ **dispositif de l'annexe II liste A**
device of list A annex II

☐ **dispositif de l'annexe II liste B**
device of list B annex II

☐ **autotest hors annexe II**
device for self-testing not listed in annex II

☒ **autre dispositif (tous les dispositifs sauf dispositifs de l'annexe II et autotests)**
other device (all devices except annex II and self-testing devices

Nom et adresse du fabricant ou du mandataire :
Name and address of the manufacturer or the authorized representative:
BIOLABO SAS / Mr Jean François CHARPENTIER, Les Hautes Rives 02160 MAIZY

Nom et adresse du site de production (facultatif):
Name and address of Production site (optional):
BIOLABO SAS, Les Hautes Rives 02160 MAIZY

Je soussigné Isabelle, Oget, Directrice Affaires Réglementairescertifie que les informations mentionnées ci-dessus sont exactes et que les dispositifs médicaux de diagnostic in vitro figurant sur la(les) déclaration(s) CE de conformité sont marqués CE sous ma responsabilité au titre de la directive n°98/79/CE et répondent aux exigences essentielles de santé et de sécurité.

I the undersigned Isabelle, Oget, Director of Regulatory Affairs declare that the information above-mentioned is correct and the in vitro diagnostic medical devices on the EC declaration(s) of conformity are CE marked under my responsibility within the meaning of the European directive n°98/79/EC and fulfil the essential requirements of health and safety.

Date :30/08/2018

Signature :

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PARTIE RESERVEE A LA CCIR PARIS IDF
Section reserved for the administration

Les dispositifs médicaux de diagnostic in vitro marqués CE en conformité avec la directive 98/79/CE peuvent être mis sur le marché en France et dans les autres Etats membres de l'Union Européenne et parties à l'accord sur l'espace économique européen, et être exportés vers les pays tiers. Ce certificat de libre vente est valide à concurrence du maintien, par le fabricant des dispositifs concernés, d'une déclaration de conformité (autre dispositifs), accompagnée le cas échéant, des certificats nécessaires délivrés par un organisme notifié (dispositif de l'annexe II liste A et liste B, autotests hors annexe II). Ce certificat de libre vente est utilisable uniquement à des fins d'exportation hors Union européenne.

CCIR Paris IDF / DGA-SEDI
Service des CLV
9, rue Coquillière
75001 PARIS

Le Responsable du département
des Facilitations du Commerce Extérieur
CCIR Paris IDF

Pour le président, Nicole LUDSO

The in vitro diagnostic medical devices CE marked in conformity with the directive 98/79/EC can be placed on the French market and in the other Member states of the European Union and part of the European Free Trade Association, and be exported in the non-EC Member States. This free sale certificate is valid until the maintenance, by the manufacturer of the concerned devices, of an CE declaration of conformity (other devices) together with when appropriate, the certificates delivered by a notified body (devices of list A and B, annex II, devices for self-testing not listed in annex II). This free sale certificate can only be used for exportation outside European Union.

BIOLABO - Désignation des Dispositifs / Devices Designation p1/5

REF	DESIGNATION FR	DESIGNATION GB
80351	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
80001	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
87601	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
LP80501	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
LP80601	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
80002	ALBUMINE Méthode BCG	ALBUMIN BCG Method
99029	ALCOOL Ethanol	ALCOHOL Ethanol
99059	ALCOOL Ethanol	ALCOHOL Ethanol
80027	ALT TGP (IFCC) Monoréactif	ALT GPT (IFCC) Single vial
80127	ALT TGP (IFCC) Monoréactif	ALT GPT (IFCC) Single vial
80227	ALT TGP (IFCC) Monoréactif	ALT GPT (IFCC) Single vial
80327	ALT TGP (IFCC) Monoréactif	ALT GPT (IFCC) Single vial
LP80507	ALT TGP (IFCC)	ALT GPT (IFCC)
LP80607	ALT TGP (IFCC)	ALT GPT (IFCC)
92027	ALT TGP Méthode Colorimétrique	ALT GPT Colorimetric Method
99523	AMYLASE CNPG3	AMYLASE CNPG3
99123	AMYLASE CNPG3	AMYLASE CNPG3
99223	AMYLASE CNPG3	AMYLASE CNPG3
LP99553	AMYLASE CNPG3	AMYLASE CNPG3
80023	AMYLASE Méthode E-PNPG7	AMYLASE E-PNPG7 Method
80123	AMYLASE Méthode E-PNPG7	AMYLASE E-PNPG7 Method
80223	AMYLASE Méthode E-PNPG7	AMYLASE E-PNPG7 Method
99261	AMMONIAC Méthode Enzymatique	AMMONIA Enzymatic Method
80025	AST TGO (IFCC) Monoréactif	AST GOT (IFCC) Single vial
80125	AST TGO (IFCC) Monoréactif	AST GOT (IFCC) Single vial
80225	AST TGO (IFCC) Monoréactif	AST GOT (IFCC) Single vial
80325	AST TGO (IFCC) Monoréactif	AST GOT (IFCC) Single vial
LP80505	AST TGO (IFCC)	AST GOT (IFCC)
LP80605	AST TGO (IFCC)	AST GOT (IFCC)
92025	AST TGO Méthode Colorimétrique	AST GOT Colorimetric Method
92026	Solution Soude 0,4 N	NaOH Solution 0.4 N
99832	BICARBONATE Méthode Enzymatique	BICARBONATE Enzymatic Method
99852	BICARBONATE Méthode Enzymatique	BICARBONATE Enzymatic Method
80403	BILIRUBINE TOTALE ET DIRECTE Méthode Acide Sulfanilique	TOTAL AND DIRECT BILIRUBIN Sulfanilic Acid Method
80443	BILIRUBINE TOTALE Méthode Acide Sulfanilique	TOTAL BILIRUBIN Sulfanilic Acid Method
80553	BILIRUBINE DIRECTE Méthode Acide Sulfanilique	DIRECT BILIRUBIN Sulfanilic Acid Method
97443	BILIRUBINE TOTALE Méthode DCA	TOTAL BILIRUBIN DCA Method
97553	BILIRUBINE DIRECTE Méthode DCA	DIRECT BILIRUBIN DCA Method
90004	CALCIUM Méthode Arsenazo III	CALCIUM Arsenazo III Method
80004	CALCIUM Méthode CPC	CALCIUM CPC Method
80005	CHLORURES Méthode Colorimétrique	CHLORIDE Colorimetric Method
80106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
LP80106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
87656	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
88656	CHOLESTEROL Non estérifié CHOD-PAP	Non Esterified CHOLESTEROL CHOD-PAP
99656	CHOLESTEROL Non estérifié CHOD-PAP	Non Esterified CHOLESTEROL CHOD-PAP
87356	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
90206	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
90406	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
90426	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
86536	CHOLESTEROL-HDL (PTA) Précipitant	CHOLESTEROL-HDL (PTA) Precipitant
86516	CHOLESTEROL-HDL (PTA) Précipitant	CHOLESTEROL-HDL (PTA) Precipitant
90416	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
90816	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
82526	CHOLINESTERASE Butyrylthiocholine	CHOLINESTERASE Butyrylthiocholine
97217	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
97317	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method

BIOLABO - Désignation des Dispositifs / Devices Designation p2/5

REF	DESIGNATION FR	DESIGNATION GB
92207	CK-NAC IFCC Monoréactif	CK-NAC IFCC Single Vial
92307	CK-NAC IFCC Monoréactif	CK-NAC IFCC Single Vial
80107	CREATININE Méthode cinétique	CREATININE Kinetic method
80008	FER (SFBC) Bathophénanthroline	IRON (SFBC) Bathophenanthrolin
92108	FER Méthode directe (Férène)	IRON Direct Method (Ferene)
92308	C.T.F. Capacité Totale de Fixation du Fer	T.I.B.C. Total Iron Binding Capacity
97408	C.L.F. Capacité Latente de Fixation du Fer	U.I.B.C Unsaturated Iron Binding Capacity
97089	G6-PDH Méthode cinétique U.V.	G6-PDH U.V. Kinetic Method
97099	G6-PDH lyophilisée Méthode cinétique U.V.	Lyophilised G6-PDH U.V. Kinetic Method
81110	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
81210	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
81310	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
80009	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
87109	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
87409	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
16GL8	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
LP80209	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
LP87809	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
3502200	HEMOGLOBINE Méthode Colorimétrique (Cyanméthémoglobine)	HAEMOGLOBIN Colorimetric Method (Cyanmethemoglobin)
82250	HEMOGLOBINE Méthode Colorimétrique (Cyanméthémoglobine)	HAEMOGLOBIN Colorimetric Method (Cyanmethemoglobin)
92011	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
92111	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
92511	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
99881	LIPASE Méthode cinétique	LIPASE Kinetic Method
99891	LIPASE Méthode cinétique	LIPASE Kinetic Method
87212	MAGNESIUM Calmagite	MAGNESIUM Calmagite
98212	MAGNESIUM CALMAGITE Haute Stabilité - Haute Linéarité	MAGNESIUM CALMAGITE High Stability – High Linearity
92214	PHOSPHATASE ALCALINE (DEA)	ALKALINE PHOSPHATASE (DEA)
92314	PHOSPHATASE ALCALINE (DEA)	ALKALINE PHOSPHATASE (DEA)
82560	PHOSPHATASE ACIDE Méthode Cinétique	ACID PHOSPHATASE Kinetic Method
3300060	PHOSPHATASE ACIDE Méthode Point Final (PNPP)	ACID PHOSPHATASE End Point Method (PNPP)
99105	PHOSPHOLIPIDES Méthode colorimétrique enzymatique	PHOSPHOLIPIDS Colorimetric enzymatic Method
99110	PHOSPHOLIPIDES Méthode colorimétrique enzymatique	PHOSPHOLIPIDS Colorimetric enzymatic Method
80015	PHOSPHORE Inorganique Méthode U.V.	Inorganic PHOSPHORUS U.V. Method
80016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEIN Biuret Method
LP87016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEIN Biuret Method
97016	PROTEINES U.S. Méthode Rouge de Pyrogallol	U.S. PROTEIN Pyrogallol Red Method
80019	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
87319	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
LP80519	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
LP80619	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
80221	UREE Méthode colorimétrique	UREA Colorimetric Method
80321	UREE Méthode colorimétrique	UREA Colorimetric Method
92032	UREE U.V. Méthode Cinétique	UREA U.V. Kinetic Method
92132	UREE U.V. Méthode Cinétique	UREA U.V. Kinetic Method
99032	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
99132	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
LP99532	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
LP99632	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
92315	KIT CALCULS URINAIRES Méthode qualitative chimique	STONE ANALYSIS SET Chemical qualitative method
92330	KIT CALCULS URINAIRES Méthode qualitative chimique	STONE ANALYSIS SET Chemical qualitative method

BIOLABO - Désignation des Dispositifs / Devices Designation p3/5

REF	DESIGNATION FR	DESIGNATION GB
95010	BIOLABO EXATROL-N Taux 1	BIOLABO EXATROL-N Level 1
95011	BIOLABO EXATROL-P Taux 2	BIOLABO EXATROL-P Level 2
95015	BIOLABO MULTICALIBRATOR Calibrateur Multiparamétrique	BIOLABO MULTICALIBRATOR Multiparametric calibrator
95020	BIOLABO EEQ Evaluation externe de la qualité	BIOLABO EQA External Quality Assessment
95403	BIOLABO CONTROLE PEDIATRIQUE	BIOLABO PAEDIATRIC CONTROL
95406	CALIBRATEUR CHOLESTEROL-HDL	HDL-CHOLESTEROL CALIBRATOR
95806	CALIBRATEUR CHOLESTEROL-LDL	LDL-CHOLESTEROL CALIBRATOR
95506	CALIBRATEUR HDL LDL CK-MB	HDL LDL CK-MB CALIBRATOR
95516	Sérum de contrôle HDL LDL CK-MB Lipides Taux 1	Control serum HDL LDL CK-MB Lipids Level 1
95526	Sérum de contrôle HDL LDL CK-MB Lipides Taux 2	Control serum HDL LDL CK-MB Lipids Level 2
95801	Calibrant LIPASE	LIPASE Calibrator
95013	Contrôle Normal AMMONIAC ALCOOL BICARBONATE	Normal Control AMMONIA ALCOHOL BICARBONATE
95023	Contrôle Pathologique AMMONIAC ALCOOL BICARBONATE	Pathological Control AMMONIA ALCOHOL BICARBONATE
95089	G6-PDH Contrôle normal (hémolysat humain lyophilisé)	G6-PDH Normal control (Lyophilised human hemolysed blood)
95289	G6-PDH Contrôle Déficient (hémolysat humain lyophilisé)	G6-PDH Deficient control (Lyophilised human hemolysed blood)
95012	Contrôle urinaire Taux 1 et Taux 2	Urinary Control Level 1 and Level 2
95315	KIT CALCULS URINAIRES Contrôles Positifs et Négatifs	STONE ANALYSIS SET Positive and Negative Controls
13880	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13885	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13881	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13702	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13704	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13712	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13883	TAMPON OWREN KOLLER	OWREN KOLLER BUFFER
13560	BIO-CK TCA Kaolin	BIO-CK APTT Kaolin
13570	BIO-CK TCA Kaolin	BIO-CK APTT Kaolin
13660	BIO-SIL TCA Silice	BIO-SIL APTT Silica
13670	BIO-SIL TCA Silice	BIO-SIL APTT Silica
13565	CHLORURE DE CALCIUM 0,025M	CALCIUM CHLORIDE 0.025M
13450	BIO-FIBRI Dosage Chronométrique du Fibrinogène	BIO-FIBRI Chronometric determination of Fibrinogen
13451	BIO-FIBRI Dosage Chronométrique du Fibrinogène	BIO-FIBRI Chronometric determination of Fibrinogen
13980	BIO-TT Temps de Thrombine	BIO-TT Thrombin Time
13965	TP-CALSET Set de Plasmas de Référence	TP-CALSET Standard Set
13970	BIO-CAL Plasma de référence	BIO-CAL Reference Plasma
13961	PLASMA CONTRÔLE Taux 1	CONTROL PLASMA Level 1
13962	PLASMA CONTRÔLE Taux 2	CONTROL PLASMA Level 2
13963	PLASMA CONTRÔLE Taux 3	CONTROL PLASMA Level 3
13210	D-DIMER Test Immunoturbidimétrique	D-DIMER Turbidimetric Immunoassay
13211	D-DIMER Control 1	D-DIMER Control 1
13212	D-DIMER Control 2	D-DIMER Control 2
13302	FACTOR II Plasma Déficient	FACTOR II Deficient plasma
13305	FACTOR V Plasma Déficient	FACTOR V Deficient plasma
13307	FACTOR VII Plasma Déficient	FACTOR VII Deficient plasma

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REF	DESIGNATION FR	DESIGNATION GB
13308	FACTOR VIII Plasma Déficient	FACTOR VIII Deficient plasma
13309	FACTOR IX Plasma Déficient	FACTOR IX Deficient plasma
13310	FACTOR X Plasma Déficient	FACTOR X Deficient plasma
13311	FACTOR XI Plasma Déficient	FACTOR XI Deficient plasma
13312	FACTOR XII Plasma Déficient	FACTOR XII Deficient plasma
13971	COATROL 1 Taux 1	COATROL 1 Level 1
13972	COATROL 2 Taux 2	COATROL 2 Level 2
9905TH	S. Typhi H (d.H)	S. Typhi H (d.H)
9905TO	S. Typhi O (9,12-O)	S. Typhi O (9,12-O)
9905AH	S. Paratyphi AH (a-H)	S. Paratyphi AH (a-H)
9905AO	S. Paratyphi AO (1,2,12-O)	S. Paratyphi AO (1,2,12-O)
9905BH	S. Paratyphi BH (b-H)	S. Paratyphi BH (b-H)
9905BO	S. Paratyphi BO (1,4,5-O)	S. Paratyphi BO (1,4,5-O)
9905CH	S. Paratyphi CH (c-H)	S. Paratyphi CH (c-H)
9905CO	S. Paratyphi CO (6,7-O)	S. Paratyphi CO (6,7-O)
9905BA	Brucella abortus	Brucella Abortus
9905PK	Proteus OXK	Proteus OXK
9905P19	Proteus OX19	Proteus OX19
9905P2	Proteus OX2	Proteus OX2
9905BM	Brucella Melitensis	Brucella Melitensis
9905RB	Rose Bengal (B. Abortus)	Rose Bengal (B. Abortus)
9901PC	Contrôle Positif Polyvalent	Positive Polyvalent Control
9901NC	Contrôle Négatif Polyvalent	Negative Polyvalent Control
99054	ANTIGENES FEBRILES Pour Tests de Widal Félix	STAINED FEBRILE ANTIGENS For Widal Felix Tests
99056	ANTIGENES FEBRILES Pour Tests de Widal Félix	STAINED FEBRILE ANTIGENS For Widal Felix Tests
99058	ANTIGENES FEBRILES Pour Tests de Widal Félix	STAINED FEBRILE ANTIGENS For Widal Felix Tests
081050	ASLO-LATEX	ASLO-LATEX
097100	CRP-LATEX	CRP-LATEX
098100	FR-LATEX	FR-LATEX
3800100	RPR-CHARBON	RPR-CHARBON
3800150	RPR-CHARBON	RPR-CHARBON
4500100	TPHA	TPHA
4500200	TPHA	TPHA
085100	HCG-LATEX	HCG-LATEX
RF050E	Facteurs Rhumatoides (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
RF520E	Facteurs Rhumatoides (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
RF CALSET51	BIOLABO FR Kit de Calibration	BIOLABO RF Standard Set
RF CALSH1	BIOLABO FR Calibrant Super Haut	BIOLABO RF Standard Super High
RF CONT1	BIOLABO FR Contrôle	BIOLABO RF Control
RF CONT5	BIOLABO FR Contrôle	BIOLABO RF Control
CRP050E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
CRP620E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
CRP CALSET51	BIOLABO CRP Kit de Calibration	BIOLABO CRP Standard Set
CRP CALSH1	BIOLABO CRP Calibrant Super Haut	BIOLABO CRP Standard Super High
CRP CONTL1	BIOLABO CRP Contrôle Bas	BIOLABO CRP Control Low
CRP CONTL5	BIOLABO CRP Contrôle Bas	BIOLABO CRP Control Low
CRP CONTH1	BIOLABO CRP Contrôle Haut	BIOLABO CRP Control High
CRP CONTH5	BIOLABO CRP Contrôle Haut	BIOLABO CRP Control High
ASLO050E	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
ASLO620E	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
ASLO CALH1	BIOLABO ASLO Calibrant Haut	BIOLABO ASLO Standard High
ASLO CALSH1	BIOLABO ASLO Calibrant Super Haut	BIOLABO ASLO Standard Super High

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REF	DESIGNATION FR	DESIGNATION GB
ASLO CALSET41	BIOLABO ASLO Kit de Calibration	BIOLABO ASLO Standard Set
ASLO CONT1	BIOLABO ASLO Contrôle	BIOLABO ASLO Control
ASLO CONT5	BIOLABO ASLO Contrôle	BIOLABO ASLO Control
APOA1620E	APOLIPOPROTEINE A1 Test Immunoturbidimétrique	APOLIPOPROTEINE A1 Turbidimetric Immunoassay
APOB620E	APOLIPOPROTEINE B Test Immunoturbidimétrique	APOLIPOPROTEINE B Turbidimetric Immunoassay
APOA1050E	APOLIPOPROTEINE A1 Test Immunoturbidimétrique	APOLIPOPROTEINE A1 Turbidimetric Immunoassay
APOB050E	APOLIPOPROTEINE B Test Immunoturbidimétrique	APOLIPOPROTEINE B Turbidimetric Immunoassay
A1B CALH1	BIOLABO A1B Calibrant Haut	BIOLABO A1B Standard High
A1B CONT1	BIOLABO A1B Contrôle	BIOLABO A1B Control
23010	MICROALBUMINE Test Immunoturbidimétrique	MICROALBUMIN Turbidimetric Immunoassay
23011	MICROALBUMINE Test Immunoturbidimétrique	MICROALBUMIN Turbidimetric Immunoassay
23012	MICROALBUMINE Calibrant Super Haut	MICROALBUMIN Standard Super High
23013	MICROALBUMINE Kit de calibration	MICROALBUMIN Standard Set
23014	MICROALBUMINE Contrôle	MICROALBUMIN Control
22050	HbA1c ENZYM	HbA1c ENZYM
22052	HbA1c ENZYM Kit de calibration	HbA1c ENZYM Standard Set
22010	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
22011	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
22012	HbA1c Kit de calibration	HbA1c Standard Set
22013	HbA1c Kit de contrôle	HbA1c Control Set
KENZA MAX	KENZA MAX BioChemisTry PHOTOMETRE	KENZA MAX BioChemisTry PHOTOMETER
KENZA 120TX	KENZA 120TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 120TX - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 240TX	KENZA 240TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 240TX - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 240ISE	KENZA 240ISE - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE avec module ISE	KENZA 240ISE - AUTOMATIC BIOCHEMISTRY ANALYSER with ISE Module
KENZA 450TX	KENZA 450TX	KENZA 450TX
KENZA 450ISE	KENZA 450ISE	KENZA 450ISE
BIOSOLEA 2	BIO SOLEA 2 - COAGULOMETRE 2 CANAUX	BIO SOLEA 2 - COAGULOMETER 2 CHANNELS
BIOSOLEA 4	BIO SOLEA 4 - COAGULOMETRE 4 CANAUX	BIO SOLEA 4 - COAGULOMETER 4 CHANNELS
SOLEA 100	SOLEA 100 - ANALYSEUR AUTOMATIQUE D'HEMOSTASE	SOLEA 100 - FULL AUTOMATED COAGULATION ANALYSER
SCUP120	Serum Cup K120TX	Serum Cup K120TX
CO0080	SERUM CUPS	SERUM CUPS
CO4015	Extra Cleaning	Extra Cleaning
CO4020	Ipo Cleaning	Ipo Cleaning
CO0058	SERUM CUPS K450	SERUM CUPS K450
K450CS	Cleaning Solution K450	Cleaning Solution K450
RP240ISE	Pack Réactifs - ISE	Reagent Pack - ISE
G2058/A	Cleaning Solution - ISE	Cleaning Solution - ISE
5202	Electrode K - ISE	Electrode K - ISE
5205	Electrode Li - ISE	Electrode Li - ISE
5207	Electrode Cl - ISE	Electrode Cl - ISE
5201	Electrode Na - ISE	Electrode Na - ISE
5204	Electrode de référence	Reference Electrode
S100CS	CLEANING SOLUTION SOLEA 100	CLEANING SOLUTION SOLEA 100