

ORDIN DE PLATĂ Nr.		1	DATA EMITERII		08 Aprilie 2025	TIP.DOC. 1	
PLĂTIȚI		2,500.00	Doua mii cinci sute lei 00 bani				
PLĂTIȚOR			CODUL IBAN		MD90PR002224190846001498		
(R) BIOSISTEM MLD SRL			CODUL FISCAL		1010600028048		
			CONTUL TREZORERIAL				
PRESTATORUL PLATITOR			BC "ProCredit Bank" SA		CODUL BANCII		
					PRCBMD22XXX		
BENEFICIAR			CODUL IBAN		MD64TRPCCC518430A00412AA		
I.P. Centrul National Sanatatea Animalelor Plantelor si Siguranta Alimentelor			CODUL FISCAL		1005600030818		
			CONTUL TREZORERIAL				
PRESTATORUL BENEFICIAR			Ministerul Finantelor - Trezoreria de Stat		CODUL BANCII		
					TREZMD2XXXX		
DESTINAȚIA PLĂȚII				TIPUL TRANSFERULUI			
Pentru garantia pentru oferta la procedura de achizitie publica nr. ocdsb3wdp1MD1743589623108 din 10.04.2025				NORMAL/URGENT			
				N			
CODUL TRANZACȚIEI		DATA PRIMIRII	DATA EXECUTĂRII		L.S.		
001							
				SEMNĂTURA EMITENTULUI			
				L.S.			
SEMNĂTURA PRESTATORULUI				Mentiunile bancii: Internet-Banking			
				Nr.REF -			
MOTIVUL REFUZULUI							

Plata cu data executarii - 08-04-2025

Ordinul de plată este primit de Bancă -

EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

Hereby DECLARES

That the products stated in the annex of five (5) pages joined herewith, meet the applicable provisions of the

Directive on in Vitro Diagnostic Medical Devices (98/79/EC)

under the specifications declared by BioSystems S.A.

It means that the products:

- complies with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- is classified as Other Device (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows the procedure stated in the Annex III of the Directive without the intervention of a Notified Body.

Barcelona, November 6th, 2012



Dr. Antonio Elduque
Managing director
BioSystems S.A.



• Certified Management
System
• EN ISO 9001
• EN ISO 13485



CLINICAL CHEMISTRY – BIOCHEMISTRY:

a-Amylase-Direct	Creatine Kinase (CK)
a-Amylase-EPS	Creatine Kinase-MB (CK-MB)
a-Amylase-Pancreatic	Creatinine
Acid Phosphatase (ACP)	Fructosamine
Alanine Aminotransferase (ALT/GPT)	Fructose
Albumin	g-Glutamyltransferase (g-GT)
Alkaline Phosphatase (ALP)-AMP	Glucose
Alkaline Phosphatase (ALP)-DEA	Iron – Chromazurol
AspartateAminotranferase (AST/GOT)	Iron – Ferrozine
Bilirubin (direct)	Iron Binding Capacity
Bilirubin (total and direct)	Lactate Dehydrogenase (LDH)
Bilirubin (total)	Lactate Dehydrogenase (LDH) – IFCC
Calcium – Arsenazo	Lipase
Calcium – MTB	Magnesium
Cholesterol	Phosphorus
Cholesterol HDL	Protein (total)
Cholesterol HDL direct	Protein (urine)
Cholesterol HDL Precipitating reagent	Pyridoxal Phosphate
Cholesterol LDL direct	Triglycerides
Cholesterol LDL Precipitating reagent	Urea/BUN-Color
Cholinesterase (CHE)	Urea/BUN-UV
Citrate	Uric Acid

CLINICAL CHEMISTRY – TURBIDIMETRY:

a1-acid Glycoprotein	C-Reactive Protein (CRP)
Albumin (Microalbuminuria)	C-Reactive Protein-hs (CRP-hs)
Anti-Streptolysin O (ASO)	Ferritin
Antithrombin III	Immunoglobulin A (IgA)
Apolipoprotein A-I (Apo A-I)	Immunoglobulin G (IgG)
Apolipoprotein B (Apo B)	Immunoglobulin M (IgM)
b2-Microglobulin	Prealbumin
Complement Component C3	Rheumatoid Factors (RF)
Complement Component C4	Transferrin

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

17-Hydroxycorticosteroids	Hemoglobin A1C
17-Ketosteroids	Hemoglobin A2
5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG)	Metanephtrines
5-Hydroxyindoleacetic acid (5-HIAA)	Vanilmandelic Acid



CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

a-1-acid Glycoprotein Standard	Biochemistry Calibrator (Human)
Adenosine Deaminase (ADA) Standard	Cholesterol HDL/LDL Calibrator
Albumin (Microalbuminuria) Standard	CRP/CRP-hs Standard
Anti-Streptolysin O (ASO) Standard	Ferritin Standard
Antithrombin III Standard	Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard
Apolipoprotein A-I Standard	Prealbumin Standard
Apolipoprotein B Standard	Protein Calibrators
b2-Microglobulin Standard	Protein (urine) Standard
Bilirubin Standard	Rheumatoid Factors (RF) Standard
Biochemistry Calibrator	

CLINICAL CHEMISTRY – INSTRUMENTS:

A15	BA400
A25	BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

a-Amylase-Direct	Creatine Kinase (CK)
a-Amylase-Pancreatic	Creatine Kinase-MB (CK-MB)
Adenosine Deaminase (ADA)	Creatinine
Alanine Aminotransferase (ALT/GPT)	g-Glutamyltransferase (g-GT)
Albumin	Glucose
Alkaline Phosphatase (ALP)-AMP	Iron Ferrozine
Alkaline Phosphatase (ALP)-DEA	Lactate dehydrogenase (LDH)
Aspartate Aminotransferase (AST/GOT)	Lipase
Bilirubin (direct)	Magnesium
Bilirubin (total)	Phosphorus
Calcium-Arsenazo	Protein (total)
Cholesterol	Protein (urine)
Cholesterol HDL direct	Triglycerides
Cholesterol LDL direct	Urea/BUN UV
	Uric acid



CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

Albumin (Microalbuminuria)	Ferritin
Anti-Streptolysin O (ASO)	Hemoglobin A1C-Turbi (HbA1C-Turbi)
Antithrombin III	Immunoglobulin A (IgA)
Complement Component C3	Immunoglobulin G (IgG)
Complement Component C4	Immunoglobulin M (IgM)
C-Reactive Protein (CRP)	Rheumatoid Factors (RF)
C-Reactive Protein-hs (CRP-hs)	Transferrin

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

ADA Controls	Hemoglobin A1C Control (Normal)
Biochemistry Control Serum (Human) I	Hemoglobin A2 Control
Biochemistry Control Serum (Human) II	Lipid Control Serum I
Biochemistry Control Serum I	Lipid Control Serum II
Biochemistry Control Serum II	Protein Control Serum I
CK-MB Control Serum	Protein Control Serum II
Control Urine	Rheumatoid Control Serum I
Fertility Biochemistry Control	Rheumatoid Control Serum II
Hemoglobin A1C Control (Elevated)	

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

Anti-Adrenal Cortex Antibodies (AACA)	Anti-Thyroid Antibodies (ATA)
Anti-Endomysium Antibodies (AEA)	Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Anti-Islet Cell Antibodies (AICA)	Autoantibodies MsK/MsS (AA-MsK/MsS)
Anti-Keratin Antibodies (AKA)	Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Anti-Mitochondrial Antibodies (AMA)	Autoantibodies RK/RS (AA-RK/RS)
Anti-nDNA antibodies (nDNA)	Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)	Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)	Glomerular Basement Membrane Antibodies (GBMA)
Anti-Nuclear Antibodies RL (ANA-RL)	
Anti-Skin Antibodies (ASA)	
Anti-Smooth Muscle Antibodies (ASMA)	
Anti-Striated Muscle Antibodies (AStMA)	



AUTOIMMUNITY – ELISA:

ANA Screening	Anti-MPO Antibodies
Anti-Annexin V IgG/IgM (ANX)	Anti-Nucleosome Antibodies (NCL)
Anti-b2-Glycoprotein 1 IgG/IgM (b2GP1)	Anti-Phospholipid IgG/IgM (APLA)
Anti-Cardiolipin Antibodies (ACA-IgG/IgM)	Anti-PR3 Antibodies
Anti-Centromere B Antibodies (CENP-B)	Anti-Ribosomal P Antibodies (Rib P)
Anti-Citrullinated Protein Antibodies (ACPA)	Anti-Scl70 Antibodies
Anti-Deamidated Gliadin Peptides IgA (DGP IgA)	Anti-Sm Antibodies
Anti-Deamidated Gliadin Peptides IgG (DGP IgG)	Anti-Sm/RNP Antibodies
Anti-dsDNA Antibodies	Anti-SSA (Ro) Antibodies
Anti-GBM Antibodies - EIA (GBM)	Anti-SSB (La) Antibodies
Anti-Gliadin Antibodies (AGA-IgG/IgA)	Anti-Thyroglobulin Antibodies (Anti-Tg)
Anti-Histones Antibodies (HIST)	Anti-Thyroid Peroxidase Antibodies (Anti-TPO)
Anti-Insulin Antibodies (INS)	Anti-tTransglutaminase IgA Antibodies (Anti- tTG IgA)
Anti-Jo1 Antibodies	Anti-tTransglutaminase IgG Antibodies (Anti- tTG IgG)
Anti-M2 Antibodies (M2)	ASCA-IgG/IgA (ASCA)
	ENA 4-Profile
	ENA 6-Screening

AUTOINMUNIDAD – INSTRUMENTOS: AUTOIMMUNITY – INSTRUMENTS:

iPRO



RAPID TESTS – LATEX AGGLUTINATION:

Anti-Streptolysin O (ASO) - Slide
C-Reactive Protein (CRP) - Slide

Rheumatoid factors (RF) - Slide

INFECTIOUS IMMUNOLOGY – SYPHILIS:

RPR-Carbon

TPHA

INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:

Febrile Serodiagnostics Multiscreening
Febrile Serodiagnostics Salmonella
Brucella abortus
Brucella abortus, Rose Bengal
Proteus Ox19
Salmonella paratyphi AH
Salmonella paratyphi AO
Salmonella paratyphi BH
Salmonella paratyphi BO
Salmonella paratyphi CH
Salmonella paratyphi CO
Salmonella typhi H
Salmonella typhi O
Brucella Positive Control
Proteus Positive Control
Salmonella Positive Control
Serology Negative Control

Prin prezenta compania Biosystems SA producătorul Analizorului biochimic A-15 / A-25 / BA-400 confirmă faptul, că produsele următoare sunt certificate de DECLARATIA DE CONFORMITATE CE № Ref . I-010 fiind parte integrală și indispensabilă al aparatului A-15 / A-25 / BA-400:

1. Rotor de reacție AC11485
2. Cuvă pentru ser AC10770
3. Soluție concentrată de spălare BO13416
4. Soluție de sistem BO11524
5. Lampă Halogenă LA10429

Produsele sus menționate sunt confecționate in conformitate cu standardele ISO 9001 si ISO 13485.



Xavier Palomar
Area Manager
27-April-2011



Prin prezenta compania Biosystems SA producătorul Analizorului biochimic A-15 / A-25 / BA-400 confirmă faptul, că produsele următoare sunt certificate de DECLARATIA DE CONFORMITATE CE № Ref . I-010 fiind parte integrală și indispensabilă al aparatului A-15 / A-25 / BA-400:

1. Rotor de reacție AC11485
2. Cuvă pentru ser AC10770
3. Soluție concentrată de spălare BO13416
4. Soluție de sistem BO11524
5. Lampă Halogenă LA10429
6. Ac pentru dozare AC11500
7. Reactivi biochimici, turbidimetrici, cromatografici, standarde, controale, aglutinație latex, indicate in anexa declarației de conformitate CE.

Produsele sus menționate sunt confecționate in conformitate cu standardele ISO 9001 si ISO 13485.



Xavier Palomar
Area Manager
27-April-2011





WINE CONTROL (WHITE, RED)

VINO CONTROL (BLANCO, TINTO)

BLANCO	TINTO
COD 12821 10 x 5 mL	COD 12822 10 x 5 mL
CONSERVAR A 2-8°C	
Sólo para uso <i>in vitro</i> en el laboratorio	

USO PREVISTO

El Vino Control (Blanco o Tinto) está destinado al control de calidad y se suministra con unos intervalos sugeridos de valores aceptables.

COMPOSICIÓN

Vino Control. Vino que contiene diversos componentes a concentraciones adecuadas para el control de la calidad en los laboratorios y que no contiene conservantes que puedan interferir en las determinaciones.

PREPARACIÓN Y USO

1. El control está listo para su uso.
2. Utilizar el control de forma idéntica a las muestras vínicas

CONSERVACIÓN Y ESTABILIDAD

Conservar a 2-8°C.

El control es estable hasta la fecha de caducidad indicada en la etiqueta.

Los componentes del material una vez abierto son estables 30 días a 2-8°C.

La presencia de precipitados no es indicativo de deterioro.

VALORES ASIGNADOS

Los valores de concentración asignados para cada componente y su trazabilidad se muestran en las hojas de valores adjuntas. La trazabilidad solo se asegura empleando los reactivos y procedimientos de medida recomendados por BioSystems.

Los intervalos de valores aceptables que se sugieren han sido elaborados en base a la experiencia previa en variabilidad interlaboratorio y se indican únicamente a título orientativo. Cada laboratorio debe establecer sus propios parámetros de precisión.

WINE CONTROL (WHITE, RED)

WHITE	RED
COD 12821 10 x 5 mL	COD 12822 10 x 5 mL
STORE AT 2-8°C	
Only for <i>in vitro</i> use in the laboratory	

INTENDED USE

The Wine Control (White or Red) is intended for quality control purposes only and is supplied with suggested intervals of acceptable values.

COMPOSITION

Wine Control. Wine containing component concentrations suitable for the quality control of the laboratories, and without preservatives which might interfere with the tests.

PREPARATION AND USE

1. The control is ready to use.
2. The control is to be treated like the wine samples.

STORAGE AND STABILITY

Store at 2-8°C.

Control is stable until the expiration date given in the label.

The components of the material once opened are stable for at least 30 days at 2-8°C.

The presence of precipitates is not indicative of deterioration.

SPECIFIED VALUES

The assigned concentration values for components and their traceability are shown in the enclosed value sheets. Traceability of the results can be assured only if the BioSystems reagents and recommended measurement procedures are used.

The suggested intervals of acceptable values have been calculated from previous experience in interlaboratory variability and are given for orientation only. Each laboratory should establish its own precision parameters.





WINE CONTROL (WHITE, RED)

VIN TÉMOIN (BLANC, ROUGE)

BLANC	ROUGE
COD 12821 10 x 5 mL	COD 12822 10 x 5 mL
CONSERVER A 2-8°C	
Pour une utilisation « in vitro » en laboratoire uniquement	

USAGE PRÉVU

Le Vin Témoin (Blanc ou Rouge) est destiné au contrôle de qualité et il est fourni à des intervalles suggérés de valeurs acceptables.

COMPOSITION

Vin Témoin. Vin contenant divers composants dans des concentrations appropriées pour réaliser le contrôle de la qualité dans les laboratoires et ne contenant pas de conservateurs qui peuvent interférer dans les déterminations.

PRÉPARATION ET USAGE

1. Le vin témoin est prêt à l'emploi.
2. Utilisez le vin témoin de manière identique aux échantillons viniques.

CONSERVATION ET STABILITÉ

Conserver à 2-8°C.

Le vin témoin est stable jusqu'à la date d'expiration indiquée sur l'étiquette.

Les composants du matériel, après l'ouverture, sont stables pendant 30 jours à 2-8°C.

La présence de précipités n'est pas indicative de détérioration.

VALEURS ASSIGNÉES

Les valeurs de concentration assignées à chaque composant et leur traçabilité sont données dans les feuilles de valeurs ci-jointes. La traçabilité n'est assurée que si l'on emploie les réactifs et procédures de mesure recommandés par BioSystems.

Les intervalles de valeurs acceptables suggérés ont été calculés d'après l'expérience préalable en variabilité entre laboratoires et ne sont indiqués qu'à titre d'orientation. Chaque laboratoire doit établir ses propres paramètres de précision.

VINO DI CONTROLLO (BIANCO, ROSSO)

BIANCO	ROSSO
COD 12821 10 x 5 mL	COD 12822 10 x 5 mL
CONSERVARE A 2-8°C	
Soltanto per uso in vitro nel laboratorio	

USO PREVISTO

Il Vino di Controllo (Bianco o Rosso) è utilizzato quale controllo della qualità e viene fornito con intervalli raccomandati di valori accettabili.

COMPOSIZIONE

Vino di Controllo. Vino che contiene diversi componenti a concentrazioni idonee al controllo qualità nei laboratori e senza conservanti che possano interferire con i test.

PREPARAZIONE E USO

1. Il vino di controllo è pronto per l'uso.
2. Utilizzare il vino di controllo allo stesso modo dei campioni di vino.

CONSERVAZIONE E STABILITÀ

Conservare a 2-8°C.

Il vino di controllo è stabile fino alla data di scadenza di cui all'etichetta.

I componenti del materiale, una volta aperto sono stabili per 30 giorni a 2-8°C.

La presenza di precipitati non è un segno di deterioramento.

VALORI ASSEGNATI

I valori di concentrazione assegnati a ogni componente e la rispettiva tracciabilità sono riportati sulle schede dei valori in allegato. La tracciabilità viene garantita soltanto con i reagenti e i procedimenti di misura raccomandati da BioSystems.

Gli intervalli di valori accettabili raccomandati sono stati elaborati sulla base dell'esperienza precedente in fatto di variabilità e vengono indicati unicamente a titolo orientativo. Ogni laboratorio è tenuto a definire i propri parametri di precisione.

