

PS/TC/RB
(N° 386/2004.cert.)

I, Mrs. Concepción Grau Olivé, Assistant General Manager of Health Products of the Spanish Agency of Pharmacy and Health Products

CERTIFY:

That the company **SPINREACT, S.A.**, with registered offices at Ctra. Santa Coloma, 7, 17176 St. Esteve de Bas (Gerona), manufactures and commercialises in Spain the products for in vitro diagnosis listed in the appendix which comprises 2 pages, which have the EC marking according to the **98/79/EC Directive** of the European Parliament and of the Council of 27th of October of 1998 on health products for in vitro diagnosis (published in the Official Bulletin of the European Communities of 7-12-1998), authorising their sale in the countries of the European Union without any type of applicable export restrictions.

For these products, the company has notified the relevant authorities for health products in Spain of the registration data of those liable for their commercialisation, as per what is set forth in Article 9 of Royal Decree 1662/2000 of the 29th of September, on health products for in vitro diagnosis (published by the Spanish Official Bulletin of 30th of September of 2000), which transposes Article 10.1 of the aforementioned directive governing the registration of manufacturers and products.

And so that it may serve the appropriate purposes and at the request of the interested party I issue this certificate in Madrid, on this twenty-fifth day of May, two thousand and four.

[stamp:]
Spanish agency of pharmacy
and health products
Subdivision of Health Products (illegible signature)

JUAN ROBERT ARNAVAT
INGENIERO INGENIERO INDUSTRIAL
TRADING FIDUCIARY JURIST
GENERAL MANAGERS MANAGER
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APPENDIX TO THE CERTIFICATION ISSUED FOR THE
COMPANY SPINREACT, S.A., DATED 25/05/2004

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SPINREACT

BIOCHEMISTRY

SUBSTRATES

Uric acid
Albumin
Bilirubin
Calcium
Chloride
Copper
Cholesterol
HDL Cholesterol
LDL Cholesterol
Creatinine
Phospholipids
Phosphorus
Fructosamine
Glucose
Haemoglobin
Glycated Haemoglobin (Hb A_{1c})
Iron
Lactate
Total lipids
Magnesium
Total proteins
Urine and CSF proteins
TIBC
Triglycerides
Urea
Zinc

IMMUNOCHEMISTRY

IMMUNO TURBIDIMETRY

Antithrombin III
Afa-1-Amylase
Afa-1- A-cid Glycoprotein
Afa-2- Macroglobulin
Cereuloplasmin
C1 Esterase
C3 & C4 Complements
PCR / PCR ULTRA
Haptoglobin
A / G / M Immunoglobulins
Kappa
Lambda
Pre-albumin
Transferrin
Microalbumin
Apoproteins. A1 / B / C-II / C-III / E

QUALITY CONTROL

Calibrators
Control sera

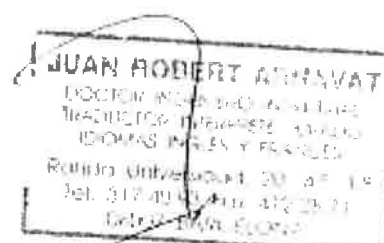
TURBILATEX

ASO
Beta-2 Microglobulin
Ferritin (FER)
Immunoglobulin E
Lipoprotein (a)
Myoglobin
Microalbumin
PCR / PCR ultra
FR
Alpha-Fetoprotein (AFP)
Glycosylated Haemoglobin

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Spanish Agency of Pharmacy and Health
Products

General Subdivision of Health Products]



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ENZYMES

Amylase
Cholinesterase
Creatine Kinase (CK)
Creatine Kinase (CK-MB)
Acid Phosphatase
Alkaline Phosphatase
GT Gamma
GOT/AST
GPT/ALT
HBDH
LAP
LDH
Lipase
Phi

QUALITY CONTROL

SPINROL CALIBRATOR
SPINROL NORMAL
SPINROL PATHOLOGICAL
SPINROL 'H' CALIBRATOR
SPINROL 'H' NORMAL
SPINROL 'H' PATHOLOGICAL
CONTROL SERUM CK/CK MB
CONTROL SERUM BILIRUBIN
LIPID CONTROL
HDL/LDL CALIBRATOR
STANDARD SOLUTIONS

QUALITY CONTROL

Calibrators
Control sera

SEROLOGY

ASO LATEX
PCR LATEX
RF LATEX
WAALER ROSE
RPR CARBON
VDRL
TOXO LATEX
M II LATEX
HBs Ag LATEX
hCG LATEX
BENGALI ROSE
TIPA
BACTERIAL ANTIGENS

QUALITY CONTROL

Positive controls
Negative controls

[stamp:

Spanish Agency of Pharmacy and Health
Products
General Subdivision of Health Products]

