



**CYPRESS  
DIAGNOSTICS**

**EC DECLARATION OF CONFORMITY**  
According to Annex III of the IVD Directive 98/79/EC

**GIÁM ĐỐC**

This is to certify that following IVD products:

See attached list

Manufactured by:

**Cypress Diagnostics**  
Langdorpsesteenweg 160  
3201 Langdorp  
Belgium



*Nguyễn Văn Khanh*

1. Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC.  
This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
2. Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:
  - availability of the technical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive.
  - the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
  - the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).
3. Cypress Diagnostics has a Quality System in place based on ISO 9001:2008 and 13485:2003 issued by Lloyd's Register Quality Assurance.
4. This Declaration of Conformity is signed below, certifying that the requirements of Annex I and Annex III have been met and documented.

Date: 05/03/2014

  
Herman Missine  
Managing Director



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<u>Biochemistry</u>			
HB001	Albumin kit 1 x 1000 ml	HBE05	$\gamma$ -GT carboxy Kit
HB0010	Albumin Kit 2 x 125 ml	HBE06	GOT (ast) Kit
HB0020	Bilirubin (Total&Direct)	HBE07	GPT (alt) Kit
HB0260	Bilirubin direct	HBE08	LDH (Lactate dehydrogenase)
HB0270	Bilirubin total	HBE09	Lipase
HB003	Calcium Kit (Arsenazo III)	HBE10	Creatine Kinase-MB
HB0030	Calcium Kit (Arsenazo III)	HBE11	G6-PDH kit
HB0040	Calcium Kit (O-Cresolphthaleine)	HBS01	Calibrator Total Bilirubin
HB005	Chloride	HBS02	Standard Haemoglobin
HB006	Cholesterol Kit	HBS03	HDL/LDL Calibrator
HB007	HDL-cholesterol	HBC01	Human Normal Control serum
HB028	LDL-Cholesterol Kit	HBC02	Human Pathologic Control serum
HB0080	Creatinine Kit	HBC03	Human Calibrator
HB009	Glucose 2 x 125 ml	HBC04	Normal bovine serum
HB010	Glucose 4 x 250 ml	HBC05	Pathological bovine serum
HB011	Haemoglobin	HBC06	Calibrator bovine source
HB012	Iron	HBC07	Lipid Control
HB0130	Magnesium Kit	HBC08	CK (NAC/MB) Control
HB014	Phosphorus	HBC09	G6-PDH control kit
HB015	Potassium		
HB016	Sodium	HBL01	Cholesterol Liquid Kit
HB017	TIBC	HBL010	Cholesterol Liquid Kit
HB018	Total lipids	HBL02	Uric Acid Liquid Kit
HB019	Total protein 1 x 1000 ml	HBL020	Uric Acid Liquid Kit
HB0190	Total protein 2 x 125 ml	HBL03	Urea Liquid Kit
HB020	Total protein in urine and CSF	HBL030	Urea Liquid Kit
HB021	Triglycerides	HBL04	Glucose Liquid Kit 2 x 125 ml
HB022	Urea 4 x 250 ml	HBL05	Glucose Liquid Kit 1 x 1000 ml
HB029	Urea 2 x 125 ml		
HB023	Uric acid Kit (12 x 20 ml)	HBL06	Triglycerides Liquid Kit
HB024	Uric acid Kit (2 x 125 ml)	HBEL01	GOT (ast) Liquid Kit
HB030	Phospholipids	HBEL010	GOT (ast) Liquid Kit
HB031	Glycated Haemoglobin	HBEL02	GPT (alt) Liquid Kit
HB0320	Magnesium Xylidyl Blue kit	HBEL020	GPT (alt) Liquid Kit
HB033	Potassium Enzymtic kit	HBEL03	CK-NAC Liquid Kit
HB034	Sodium Enzymatic kit	HBEL04	LDH Liquid Kit
		HBEL05	CK-MB Liquid Kit
HBE01	Acid Phosphatase	HBEL06	$\gamma$ -GT Liquid Kit
HBE02	Alkaline phosphatase (ALP)		
HBE03	$\alpha$ -Amylase		
HBE04	Creatine Kinase-NAC		

Date: 05/03/2014

1/4



## CYPRESS DIAGNOSTICS

### Biochemistry Analyzer

CY004	CYANStart Biochemistry semi-automate	22152-500	RPR Carbon 500t
CY005	CYANPro Biochemistry automate	22152S	RPR Carbon 5 ml
CY008	CYANExpert 130	22162	Waalser Rose – 50 tests
CY008-WS-I	Rinse solution	22172	VDRL
CY008-WS-III	Cleaning solution	22192	TPHA
CY008-WS-IV	Acid solution	221920	TPHA 200t
		22201	Rose Bengal – 50 tests
		22212	D-Dimer Latex
		22222	I.M Latex (Infectious Mononucleosis)

### Coagulation

HC00100	APTT
HC00200	PT
HC00300	Fibrinogen
HC00500	Coagulation Control
HC00600	Coagulation Calibrator

### Coagulation Analyzer

CY003	CyanCoag
CY003-C01	Cuvettes and balls for 500 tests

### Stains (Histopathology-Hematology-Bacteriology)

HS001	Gram PVP
HS002	TB-Ziehl-Neelsen
HS003	Giemsa
HS004	May-Grünwald
HS005	Quick Panoptic Conc. (1:10)
HS006	Harris' Hematoxylin
HS007	Orange G-6 solution
HS008	Polychromic solution EA-36
HS009	Polychromic solution EA-50
HS010	Hayem
HS011	Türk
HS013	Crystal Violet
HS014	Safranin
HS015	Carbol Fuchsin
HS016	Methylene Blue (Kühne's)
HS017	Carbol Fuchsin Kinyoun
HS018	TB Decolorizer
HS019	Brilliant Green
HS021	Carbol Gentian Violet
HS022	Lugol PVP Solution
HS023	Wright

### Latex testing

22122	ASO Latex
22102	CRP Latex
22112	RF
22132	hCG slide
22152	RPR Carbon 150t

### Quick tests

341-025	Malaria Falciparum
174-20	Chagas
344	Dengue IgG&IgM Combo
132-100	hCG Dipstrips Urine
132-100/100	hCG Dipstrips Urine
132-100/50	hCG Dipstrips Urine
132-100/20	hCG Dipstrips Urine
132-MANE	hCG Dipstrips 25 in kit
132-100/4x25	hCG Strip Urine/Serum 4x25t
132-200	hCG Cards Urine/Serum
132-200/100	hCG Cards Urine/Serum
132-200/50	hCG Cards Urine/Serum
132-200/20	hCG Cards Urine/Serum

333	H. Pylori
335	Rota Kit – 25 tests
336	Adeno/GRP Kit – 25 tests
337	Strep A
339	Crypto Kit – 25 tests
340	Leishmania - visceral
345	Malaria Total Quick Test
346	Cardiac Troponin I
347	FOB
349	Giardia
351	Influenza A Kit
353	Syphilis Quick Test
354	Hepatitis A Ag
355	Leptospira IgM Test

### Bacterial Antigens

5011	Salmonella Paratyphi AH
5021	Salmonella Paratyphi AO
5031	Salmonella Paratyphi BH
5041	Salmonella Paratyphi BO
5051	Salmonella Paratyphi CH
5061	Salmonella Paratyphi CO
5071	Salmonella Typhi H
5081	Salmonella Typhi O
5101	Proteus OX 2



## CYPRESS DIAGNOSTICS

5111 Proteus OX 19  
5121 Proteus OXK  
5091 Brucella Abortus  
5092 Brucella Melitensis  
5901 Bacterial antigen positive control  
5902 Bacterial antigen negative control  
BA-SPEC Bacterial antigens

### Parasitic Elisa

HP001 Cysticercosis Ab  
(Taenia solium IgG)  
HP003 Amebiasis Ab  
HP002 Echinococcosis  
HP004 Trichinella Ab  
HP005 Leishmania Ab  
HP006 Toxocara Ab  
HP007 Giardiasis Ag  
HP008 Cryptosporidium  
HP010 Verotoxin

### Drugs of Abuse

DOA-2 Drug Screen Card MOR/THC  
DOA-10 Drug Screen Card 10 parameters

### Multi-parameter test device

Urine-1B Blood  
Urine-1G Glucose  
Urine-1P Proteine  
Urine-2AC Microalbumin-Creatinine  
Urine-2GC Glucose-Ketone  
Urine-2GP Glucose-Proteine  
Urine-3 Glucose-Proteine-pH  
Urine-3/50 Glucose-Proteine-pH  
Urine-4SG Protein-Glucose-Specific gravity-pH  
Urine-9 Glucose-Bilirubin-Specific Gravity-Proteine-pH-Ketone-Blood-Nitrite-Urobilinogen  
Urine-10 Glucose-Bilirubin-Specific Gravity-Proteine-pH-Ketone-Blood-Nitrite-Urobilinogen-Leucocytes

CY002 CYANStrip Urine Strip Analyzer

### Haematology

CY006 CYANHemato  
CY006-R01 Diluent  
CY006-R02 Lyse  
CY006-R03 Cleaner  
CY006-R05 Clenz  
CY006-R04 Hypoclean  
CY006-R06 Hypoclean CC

HP011 Dengue IgM  
HP012 Dengue IgM + IgG  
HP013 Leptospira  
HP014 Diphtheria  
Allergy  
ULTOT Total IgE

### Microbiology

610.33 Mueller Hinton Agar  
610.34 Mueller Hinton Broth  
9001 to 9116 Antibiotic Discs  
19001 to 19116 Antibiotic Discs



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Turbidimetry

HT001 HbA1c Kit  
HT001S HbA1c Calibrator  
HT001C HbA1c Control

Specimen receptacles

D10145 Stool container  
D101401 Urine container



Herman Missine  
Managing Director

