



International Certifications

Certificate of Conformity



Issued in compliance with the Directive No. 98/79/EC of the European parliament and of the council on in vitro diagnostic medical devices, which is implemented by Slovak Government Decree No. 569/2001 as amended by Decree 610/2008 (collection of laws), certifies that in vitro diagnostics medical devices

Bio Chemistry Reagents

Type: Dry Powder Reagent, Liquid Stable Reagent, Immunology Reagent, Latex Turbidimetry, Aquachemical Reagent

As per Annex 1

Manufactured by

“Pathozyme Diagnostics”

Plot No.115, Kagal Hatkanangle, Industrial Estate,
Kagal, Kolhapur, Maharashtra,
India

Compliance with the Essential requirement of the Directive No. 98/79/EC of IVD as amended, which apply to them.

EC International Certification performed an assessment of the technical documentation of the diagnostics medical devices in vitro in terms of intended use under the relevant sections of the above mentioned Directive and the relevant harmonized European standards: EN ISO 14971:2012, ISO 9001:2008, EN ISO 13485:2012, EN 15223-1:2012, EN 13612:2002, EN 13640:2008, EN ISO 18113-2:2011.


This certificate is issued under following conditions:

It applies only to the above model of in vitro diagnostics device. The manufacturer must ensure compliance of the specified models of the Bio-chemistry reagents in accordance with this certificate. The certificate remains valid unless changes in technology, Quality system or the regulations invalidated it or at most until **June 2017**. After meeting the requirements of the relevant EU legislation, the manufacturer must identify every diagnostics medical device in vitro of the above models with the CE mark.

Certificate no: ECIC-2014-IVD-001

Certificate Issue Date: July, 01, 2014

Certificate Expiry Date: June, 30, 2017


Authorized Signatory
Date: 01.07.2014



The certificate remains the property of EC INTERNATIONAL CERTIFICATIONS and the certificate Validation shall be ensured by EC International Certifications. This must not be copied in Whole or in part without the written permission of the Managing Director of EC INTERNATIONAL CERTIFICATIONS. Deliberate misuse of the certificate or schedule will result in cancellation without notification. The product liability rests with the manufacturer or his representative in accordance with council Directive 2006/42/EC & 2006/95/EC.

Registered at: Office 23, Sagar Plaza, Kasarwadi, Pune, Maharashtra, India. www.ecint.co.in



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Annex 1 to Certificate No. - ECIC-2014-IVD-001

Issued for the company

“Pathozyme Diagnostics”

Plot No.115, Kagal Hatkanangle, Industrial Estate,
Kagal, Kolhapur, Maharashtra,
India

List of the products covered by the certificate

BIOCHEMISTRY REAGENTS

DRY POWDER REAGENT	
CAT NO	PRODUCT
ALP1511 ALP0510 ALP1010	ALKALINE PHOSPHATASE
AMP1511 AMP1003 AMP0510	α -AMYLASE
CHP0425 CHP0450 CHP5100	CHOLESTEROL
CNP1511 CNP1003	CK-NAC
CMP1511 CMP1003	CK-MB
CNM5151	CK- NAC & CK-MB
GGT1511 GGT1003 GGT1010	GAMMA GT
GTP0550 GTP5100 GTP4250 GTP1050	GLUCOSE (10 Mins)
GFP0550 GFP5100 GFP4250	GLUCOSE (5 Mins)
GPD0012	G-6-PD (Qualitative)
LDH1511	LDH (L \rightarrow P)
OTE0210 OTE0225 OTE0250	SGOT -TE
OTP0210 OTP0225 OTP0425	SGOT
PTE0210 PTE0225 PTE0425	SGPT -TE
PTP0210 PTP0225 PTP0425	SGPT
TGP0505 TGP0510 TGP0525	TRIGLYCERIDES
URB0100 URB0200	UREA (Berthelot)
URG0510 URG0425 URG0450	UREA -UV GLDH
UAP0510 UAP0325 UAP0430	URIC ACID

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LIQUID STABLE REAGENT	
CAT NO	PRODUCT
ALL0210 ALL0225 ALL0250	ALKALINE PHOSPHATASE - L
AML0205 AML0010 AML0210 AML0225	α -AMYLASE - L
COL0120	CHOLINESTERASE - L
CHL0310 CHL0350 CHL5100	CHOLESTEROL - L (With HDL Std. & PPT Rgt.)
CNL0210 CNL0220	CK-NAC - L
CML0210 CML0220	CK-MB - L
GGL0210 GGL0220	GAMMA GT - L
GTL5100 GTL4250	GLUCOSE - L (10 Mins)
GFL5100 GFL4250	GLUCOSE - L (5 Mins)
PTA0225 PTA0250	HDL-CHOLESTEROL - L
HDL0120 HDL0140 HDL0180	D-HDL CHOLESTEROL - L
HDS0120 HDS0220 HDS0240	D-HDL CHOLESTEROL - L (Single Reagent)
LLD0210 LLD0220	LDH (L \rightarrow P) - L
LDL0120 LDL0140 LDL0180	D-LDL CHOLESTEROL - L
LI P0110 LIP0125	LIPASE - L
OLE0225 OLE0425 OLE0450	SGOT (TE) - L
OTL0225 OTL0425 OTL0450	SGOT - L
PLE0225 PLE0425 PLE0450	SGPT (TE) - L
PTL0225 PTL0425 PTL0450	SGPT - L
TGL0310 TGL0350 TGL5100	TRIGLYCERIDES - L
UBL0100 UBL0200	UREA (Berthelot) - L
URL0225 URL0350 URL3100	UREA (UV-GLDH) - L
UAL0210 UAL0225 UAL0425	URIC ACID - L

LATEX TURBIDIMETRY	
CAT NO.	PRODUCT
AST0050	ASO Turbilatex
CRT0050	CRP Turbilatex
RFT0050	RF Turbilatex

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AQUACHEMICAL REAGENTS	
CAT NO	PRODUCT
ALB0250	ALBUMIN
APT5050	ALBUMIN & TOTAL PROTEIN
BIL0175 BIL0275	EASY BILIRUBIN
CAO0225 CAO0250	CALCIUM (With Accessories)
CAA0025 CAA0050 CAA0250	CALCIUM (Monovial With Accessories)
CRD0025 CRD0050	CHLORIDE
CRS0250 CRS0550 CRS5100	CREATININE (Single Reagent)
CRK0250 CRK0450 CRK4250	CREATININE (R1 & R2)
CRE0225 CRE0250	CREATININE (End Point)
CSF0250	C.S.F PROTEIN
FCC0250 FCC0500	FLOW CELL CLEANER
HBR1000 HBR5000	HAEMOPATH (HAEMOGLOBIN REAGENT)
HBS0010	HEAMOGLOBIN STANDARD
IRN0025	IRON
MAG0025 MAG 0050	MAGNESIUM
PHS0025 PHS0050	PHOSPHORUS
POT0025 POT0050	POTASSIUM
PST2020	POTASSIUM & SODIUM

IMMUNOLOGY REAGENT	
CAT NO.	PRODUCT
ASO0025 ASO0050 ASO0100	RepicheckK ASO
CRP0025 CRP0050 CRP0100	RepicheckK CRP
RFL0025 RFL0050 RFL0100	RepicheckK RF
RPR0050 RPR0100 RPR0500 RPR1000	RepicheckK RPR
WAS0405 WAS2205	RepicheckK Widal -S
WAT0450 WAT2250	RepicheckK Widal -T



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