

DECLARATION OF CONFORMITY

Unique identification No.: DoC2007-01

1) Manufacturer (Name, department): **Acro Biotech, LLC.**

Address: **9500 7th Street, Unit M, Rancho Cucamonga, CA 91730, U.S.A.**

and

2) European authorized representative: **CEpartner4U BV,**

Address: **Esdoornlaan 13, 3951DB Maarn, The Netherlands;**

(on product labels printed as:

CEpartner4U , Esdoornlaan 13, 3951DB Maarn, The Netherlands Tel.: +31 (0)6 516 536 26;

or as: CEpartner4U, 3951DB; 13. NL tel: +31 (0)6 – 516.536.26)

3) Product(s) (name, type or model/batch number, etc.):

- **Rapid test, Chemistry**

see appendix

4) The product(s) described above is in conformity with:

<u>Document No.</u>	<u>Title</u>	<u>Edition / Date of issue</u>
L 331; 98/79/EC	<i>In vitro</i> Diagnostic Medical Devices Directive	1998-10-27

5) Additional information (conformity procedure, Notified Body, CE certificate, etc.):

Conformity assessment procedure for CE marking: IVD Directive, Annex III.

Rancho Cucamonga, USA; 2007-02-01

(Place & date of issue (yyyy-mm-dd))

(name, function and signature of manufacturer)

Maarn, NL; 2007-02-01

Harry Teirlinck, Senior Consultant, CEpartner4U BV

(Place & date of issue (yyyy-mm-dd))

(name; function and signature of authorized representative)



Appendix (to DoC2007-01)

Date: 2007-02-01

List of devices.

Device name	Description	New Ref number	Old Ref Number	EDMS-code	First date of CE-marking
Drug of Abuse					
Amphetamine	AMP 1000, dipstick	0117	AMPDS1000	1270090100	2006-05-19
Amphetamine	AMP 1000, cassette test	0118	AMPDS1000	1270090100	2006-05-19
Amphetamine	AMP-300, Dipstick test	0217	AMPDS300	1270090100	2006-05-19
Amphetamine	AMP-300, cassette test	0218	AMPDS300	1270090100	2006-05-19
Barbiturate	BAR-300, Dipstick test	0317	BARDS300	1270090300	2006-05-19
Barbiturate	BAR-300, cassette test	0318	BARDS300	1270090300	2006-05-19
Buprenorphine	BUP-10, Dipstick test	0417	BUPDS10	1209019000	2006-05-19
Buprenorphine	BUP-10, cassette test	0418	BUPDS10	1209019000	2006-05-19
Benzodiazepine	BZD-300, Dipstick test	0517	BZDDS300	1270090400	2006-05-19
Benzodiazepine	BZD-300, cassette test	0518	BZDCS300	1270090400	2006-05-19
Benzodiazepine	BZD-200, Dipstick test	0538	BZDDS200	1270090400	2006-05-19
Benzodiazepine	BZD-200, cassette test	0539	BZDCS200	1270090400	2006-05-19
Cocaine	COC-300, Dipstick test	0617	COCCS300	1270090600	2006-05-19
Cocaine	COC-300, cassette test	0618	COCCS300	1270090600	2006-05-19
MDA		obsolete	MDADS500	1209019000	2006-05-19
MDA		obsolete	MDACS500	1209019000	2006-05-19
MDMA (Ecstasy)	MDMA Test, dipstick	0816	MDMDS500	1209019000	2006-05-19
MDMA (Ecstasy)	MDM 500, cassette test	0817	MDMCS500	1209019000	2006-05-19
Methamphetamine	MET 300, Dipstick test	0917	METDS300	1209010200	2006-09-07
Methamphetamine	MET 300, cassette test	0918	METCS300	1209010200	2006-09-07
Methamphetamine	MET500, Dipstick test	1026	METDS500	1209010200	2006-05-19
Methamphetamine	MET500, Cassette test	1027	METCS500	1209010200	2006-05-19
Methamphetamine	MET 1000, Dipstick test	1017	METDS1000	1209010200	2006-05-19
Methamphetamine	MET 1000, cassette test	1018	METCS1000	1209010200	2006-05-19
Methadone	MTD 300, Dipstick test	1117	MTDDS300	1270090700	2006-05-19
Methadone	MTD 300, cassette test	1118	MTDCS300	1270090700	2006-05-19
Opiate	OPI 2000, Dipstick test	1217	OPIDS2000	1270090800	2006-05-19
Opiate	OPI 2000, cassette test	1218	OPICS2000	1270090800	2006-05-19
Opiate	OPI 300, Dipstick test	1317	OPIDS300	1270090800	2006-05-19
Opiate	OPI 300, cassette test	1318	OPICS300	1270090800	2006-05-19
Oxycodone	OXY, Dipstick test	1417	OXYDS100	1209019000	2006-05-19
Oxycodone	OXY, cassette test	1418	OXYCS100	1209019000	2006-05-19



Device name	Description	New Ref number	Old Ref Number	EDMS-code	First date of CE-marking
Drug of Abuse					
Phencyclidine	PCP 25, Dipstick test	1517	PCPDS25	1270090900	2006-05-19
Phencyclidine	PCP 25, cassette test	1518	PCPCS25	1270090900	2006-05-19
Tricyclic Antidepressant (TCA)	TCA 1000, Dipstick test	1617	TCADS1000	1209021500	2006-05-19
Tricyclic Antidepressant (TCA)	TCA 1000, cassette test	1618	TCACS1000	1209021500	2006-05-19
Marijuana (THC)	THC 50, Dipstick test	1717	THCDS50	1270090500	2006-05-19
Marijuana (THC)	THC 50, cassette test	1718	THCCS50	1270090500	2006-05-19
Ketamine Test (KTM)	KTM, Dipstick	1769		1270090500	2007-01-31
Ketamine Test (KTM)	KTM, Cassette	1770		1270090500	2007-01-31
Propoxyphene Test (PPX)	PPX, Dipstick	1817		1270090500	2007-01-31
Propoxyphene Test (PPX)	PPX, Cassette	1818		1270090500	2007-01-31
Multi-line Drug	Multi-line Drug Test, OPI-MET Test	1851		1270090500	2007-01-31
CardLab-5	CardLab combo of 5 - Aus BZD200/COC300/MET300/OPI300/THC50	2003	CRD0501	1270097000	2006-05-19
CardLab-5	CardLab, SAMHSA, AMP1000/COC300/OPI2000/PCP25/THC50	2005	CRD0502	1270097000	2006-05-19
CardLab-5	CardLab, combo of any 5 drugs of abuse	2007	CRD0503	1270097000	2006-05-19
CardLab -5		obsolete	CRD0504	1270097000	2006-05-19
CardLab-5		obsolete	CRD0505	1270097000	2006-05-19
CardLab-6	CardLab combo of 6, Aus, AMP300/BZD200/COC300/MET300/OPI300/THC50	2012		1270097000	2007-01-31
CardLab-6	Combo of any 6 drug tests	2014	CRD0601	1270097000	2006-05-19
CardLab-6		obsolete	CRD0602	1270097000	2006-09-07
CardLab DipCard-5	Combo of any 5 drug tests	2021	DPC0501	1270097000	2006-05-19
CardLab DipCard-5	CardLab Dipcard-5 Card, 4308, BZD200/COC300/MET300/OPI300/THC50	2016	DPC0502	1270097000	2006-05-19
CardLab DipCard-5	CardLab Dipcard-5 Card, Samhsa COC300/MET1000/OPI2000/PCP25/THC50	2017	DPC0503	1270097000	2006-09-07
QCP 3 drug test		obsolete	QCP0301	1270097000	2006-05-19
QCP 4 drug test		obsolete	QCP0401	1270097000	2006-05-19



Device name	Description	New Ref number	Old Ref Number	EDMS-code	First date of CE-marking
Drug of Abuse					
QCP-5		obsolete	QCP0501	1270097000	2006-05-19
QCP- 5		obsolete	QCP0502	1270097000	2006-05-19
QCP-6		obsolete	QCP0601	1270097000	2006-05-19
QCP-7		obsolete	QCP0701	1270097000	2006-05-19
QCP-8		obsolete	QCP0801	1270097000	2006-05-19
QCP-9		obsolete	QCP0901	1270097000	2006-05-19
QCP-10		obsolete	QCP1001	1270097000	2006-05-19
QCP-11		obsolete	QCP1101	1270097000	2006-05-19
QCP-12		obsolete	QCP1201	1270097000	2006-05-19
QCP-13		obsolete	QCP1301	1270097000	2006-05-19
CupLab-3	Combo of any 3 drug tests	2130	CUP0301	1270097000	2006-05-19
CupLab-4	Combo of any 4 drug tests	2131	CUP0401	1270097000	2006-05-19
CupLab-5	Combo of 5 drug tests in accordance with 4308	2132	CUP0501	1270097000	2006-05-19
CupLab-5	CupLab 5 drug test, Samhsa Cutoff	2133	CUP0502	1270097000	2006-05-19
CupLab 6 drug test	Combo of any 6 drug tests	2134	CUP0601	1270097000	2006-05-19
CupLab 7 drug test	Combo of any 7 drug tests	2135	CUP0701	1270097000	2006-05-19
CupLab 8 drug test	Combo of any 8 drug tests	2136	CUP0801	1270097000	2006-05-19
CupLab 9 drug test	Combo of any 9 drug tests	2137	CUP0901	1270097000	2006-05-19
CupLab 10 drug test	Combo of any 10 drug tests	2138	CUP1001	1270097000	2006-05-19
CupLab 11 drug test	Combo of any 11 drug tests	2139	CUP1101	1270097000	2006-05-19
CupLab 12 drug test	Combo of any 12 drug tests	2140	CUP1201	1270097000	2006-05-19
CupLab 13 drug test	Combo of any 13 drug tests	2141	CUP1301	1270097000	2006-05-19
POC drug test, 3	Combo of any 3 drug tests	2417	POC0301	1270097000	2006-05-19
POC drug test, 3	THC-50, MET-1000, BZD-300	2418	POC0302	1270097000	2006-05-19
POC drug test, 3	THC-50, MET-300, BZD-300	2419	POC0303	1270097000	2006-05-19
POC drug test, 5	Combo of any 5 drug tests other than Aus and SAMHSA	2420	POC0501	1270097000	2006-05-19
POC drug test, 5	Combo of 5 drug tests in accordance to Aus 4308	2421	POC0502	1270097000	2006-05-19
POC drug test, 5	Combo of 5 drug tests in accordance to SAMHSA	2422	POC0503	1270097000	2006-05-19
POC drug test, 5		obsolete	POC0504	1270097000	2006-05-19
POC drug test, 6	Combo of any 6 drug tests	2424	POC0601	1270097000	2006-05-19
POC drug test, 6	POC, combo of 6 drug tests: AMP/BZD/COC/MET/OPI/THC	2425	POC0602	1270097000	2006-05-19
POC drug test, 8		obsolete	POC0801	1270097000	2006-09-07
POC drug test, 8		obsolete	POC0802	1270097000	2006-09-07
POC-12		obsolete	POC1201	1270097000	2006-05-19
Drug test, Touch Alcohol Test	Saliva alcohol test	5101	USR07	1209029000	2006-05-19



Device name	Description	New Ref number	Old Ref Number	EDMS-code	First date of CE-marking
Drug of Abuse					
UrineSure Adulterant test	Urine Adulterant Test	5102	ALC02	1209021900	2006-05-19

Device name	Description	New Ref number	Old Ref number	EDMS-code	First date of CE-marking
Fertility					
HCG Dipstick Test	HCG25 Test, dipstick	2713	HCGDS25	1270050200	2006-05-19
HCG CassetteTest	HCG25 Test, cassette	2714	HCGCS25	1270050200	2006-05-19
HCG Cup Test	HCG25, Cup Test	2722	HCGMS25	1270050200	2006-05-19
HCG		obsolete	HCGDS10	1270050200	2006-05-19
HCG		obsolete	HCGCS10	1270050200	2006-05-19
HCG		obsolete	HCGMS10	1270050200	2006-05-19
FSH Dipstick Test	FSH25, dipstick Test	2813	FSHDS25	1270050100	2006-05-19
FSH Cassette Test	FSH25, Cassette Test	2814	FSHCS25	1270050100	2006-05-19
LH Dipstick Test	LH20, Dipstick Test	2913	LHDS25	1270050400	2006-05-19
LH Cassette test	LH20, Cassette Test	2914	LHCS25	1270050400	2006-05-19
LH Cup Test	LH20, Cup Test	2922	LHMS20	1270050400	2006-05-19

Device name	Description	New Ref number	Old Ref number	EDMS-code	First date of CE-marking
Tumor Marker					
AFP Dipstick Test	AFP25, Dipstick Test	3113	AFPDS25	1203900100	2006-05-19
AFP Cassette Test	AFP25, Cassette Test	3114	AFPCS25	1203900100	2006-05-19
CEA Dipstick Test	CEA05, Dipstick Test	3213	CEADS25	1203013100	2006-05-19
CEA Cassette Test	CEA05, Cassette Test	3214	CEACS25	1203013100	2006-05-19
CEA05, Pouched device, dipstick		obsolete	CEADS25	1203013100	2006-05-19
CEA05, pouched device, cassette		obsolete	CEACS25	1203013100	2006-05-19
FOB50 TesTube Test	FOB50 test, Test device, TesTube	3413	PD	1203900400	2006-05-19
FOB50 Dipstick	FOB50 test, Dipstick Test	3414	FOBDS50	1203900400	2006-05-19
FOB50 Cassette Test	FOB50 test, Cassette Test	3415	FOBCS50	1203900400	2006-05-19



Device name	Description	New Ref number	Old Ref number	EDMS-code	First date of CE-marking
Cardiac Marker	Cardiac Marker				
CKMB10 test, Pouched device, dipstick		obsolete	CKMB10DS25	1270130100	2006-05-19
CKMB10 Cassette Test	CKMB10 test, Cassette Test	3514	CKMB10CS25	1270130100	2006-05-19
Myoglobin 100 test, Pouched device, dipstick		obsolete	MGB10010DS25	1270130200	2006-05-19
Myoglobin 100 Cassette test	Myoglobin 100 test, Cassette Test	3614	MGB10010CS25	1270130200	2006-05-19
Troponin I 01 test, Pouched device, dipstick		obsolete	Tnl 01DS25	1270130300	2006-05-19
Troponin I Cassette Test	Troponin I 01 test, Cassette Test	3714	Tnl 01CS25	1270130300	2006-05-19

Device name	Description	New Ref number	Old Ref number	EDMS-code	First date of CE-marking
Infectious Disease	Infectious Disease				
Strep A Dipstick Test	Strep A test, Dipstick Test	4013	STADS05	1570010300	2006-05-19
Strep A Cassette Test	Strep A test, Cassette Test	4014	STACS05	1570010300	2006-05-19
Strep A TesTube Test	Strep A test, TesTube	4015	STATB05	1570010300	2006-05-19
Dengue IgG/IgM Dipstick Test	Dengue IgG/IgM Test, Dipstick	4201		1570010300	2007-01-31
Dengue IgG/IgM Cassette Test	Dengue IgG/IgM Test, Cassette	4202		1570010300	2007-01-31

Device name	Description	New Ref number	Old Ref number	EDMS-code	First date of CE-marking
Chemistry	Chemistry				
Alk. Phosphatase, Endpoint	Alk. Phosphatase, End Point Test Test	5201	5201	1101010500	2006-05-19
Creatinine, Color Endpoint	Creatinine, Color End Point Test Test	5202	5202	1102010700	2006-05-19
AST/GOT, Color Endpoint	AST/GOT, Color End Point Test	5203	5203	1101011000	2006-05-19
Acid Phosphatase, Kinetic	Acid Phosphatase, Kinetic Test	5204	5204	1101010200	2006-05-19



Device name	Description	New Ref number	Old Ref number	EDMS-code	First date of CE-marking
Chemistry	Chemistry				
ALT/GPT, Color Endpoint	ALT/GPT, Color End Point Test	5205	5205	1101010300	2006-05-19
Albumin	Albumin	5206	5206	1102010100	2006-05-19
Hemoglobin	Hemoglobin	5207	5207	1301700100	2006-05-19
Alk. Phosphatase, Liquid	Alk. Phosphatase, Liquid	5208	5208	1101010500	2006-05-19
Alk. Phosphatase, Kinetic	Alk. Phosphatase, Kinetic Test	5209	5209	1101010500	2006-05-19
Alk. Phosphatase, Kinetic	Alk. Phosphatase, Kinetic Test	5210	5210	1101010500	2006-05-19
ALT/GPT, Liquid (Kinetic)	ALT/GPT, Liquid (Kinetic Test)	5211	5211	1101010300	2006-05-19
ALT/GPT, Kinetic	ALT/GPT, Kinetic Test	5212	5212	1101010300	2006-05-19
ALT/GPT, Kinetic	ALT/GPT, Kinetic Test	5213	5213	1101010300	2006-05-19
Amylase, Kinetic	Amylase, Kinetic Test	5214	5214	1101010700	2006-05-19
AST/GOT, Liquid (Kinetic)	AST/GOT, Liquid (Kinetic Test)	5215	5215	1101011000	2006-05-19
AST/GOT, Kinetic	AST/GOT, Kinetic Test	5216	5216	1101011000	2006-05-19
AST/GOT, Kinetic	AST/GOT, Kinetic Test	5217	5217	1101011000	2006-05-19
Bilirubin Direct	Bilirubin Direct	5218	5218	1102010300	2006-05-19
Bilirubin Total	Bilirubin Total	5219	5219	1102010300	2006-05-19
Bilirubin Direct&Total	Bilirubin Direct&Total	5220	5220	1102010300	2006-05-19
BUN, Liquid (Kinetic)	BUN, Liquid (Kinetic Test)	5221	5221	1102010400	2006-05-19
BUN, Kinetic	BUN, Kinetic Test	5222	5222	1102010400	2006-05-19
BUN, Kinetic	BUN, Kinetic Test	5223	5223	1102010400	2006-05-19
BUN, Urease, Color Endpoint	BUN, Urease, Color End Point Test	5224	5224	1102010400	2006-05-19
BUN, Urease, Color Endpoint	BUN, Urease, Color End Point Test	5225	5225	1102010400	2006-05-19
Calcium	Calcium	5226	5226	1103010300	2006-05-19
Carbon Dioxide	Carbon Dioxide	5227	5227	1104020100	2006-05-19
Chloride	Chloride	5228	5228	1103010400	2006-05-19
Cholesterol, Liquid	Cholesterol, Liquid	5229	5229	1102010500	2006-05-19
Cholesterol	Cholesterol	5230	5230	1102010500	2006-05-19
Cholesterol	Cholesterol	5231	5231	1102010500	2006-05-19
Cholesterol	Cholesterol	5232	5232	1102010500	2006-05-19
Cholinesterase, Kinetic	Cholinesterase, Kinetic Test	5233	5233	1101011100	2006-05-19
Creatine Kinase-NAC, Kinetic	Creatine Kinase-NAC, Kinetic Test	5234	5234	1101011300	2006-05-19
Creatine Kinase-NAC, Kinetic	Creatine Kinase-NAC, Kinetic Test	5235	5235	1101011300	2006-05-19



Device name	Description	New Ref number	Old Ref number	EDMS-code	First date of CE-marking
Chemistry	Chemistry				
CK-MB, Kinetic	CK-MB, Kinetic Test	5236	5236	1101011400	2006-05-19
CK-MB, Kinetic	CK-MB, Kinetic Test	5237	5237	1101011400	2006-05-19
Creatinine, Kinetic	Creatinine, Kinetic Test	5238	5238	1102010700	2006-05-19
Creatinine, Direct Endpoint	Creatinine, Direct End Point Test	5239	5239	1102010700	2006-05-19
g-GT, Soluble, Kinetic	g-GT, Soluble, Kinetic Test	5240	5240	1101011600	2006-05-19
g-GT, Soluble, Kinetic	g-GT, Soluble, Kinetic Test	5241	5241	1101011600	2006-05-19
g-GT, Liquid	g-GT, Liquid	5242	5242	1101011600	2006-05-19
Glucose Hexokinase, Liquid	Glucose Hexokinase, Liquid	5243	5243	1102011300	2006-05-19
Glucose Hexokinase	Glucose Hexokinase	5244	5244	1102011300	2006-05-19
Glucose Hexokinase	Glucose Hexokinase	5245	5245	1102011300	2006-05-19
Glucose Oxidase Trinder	Glucose Oxidase Trinder	5246	5246	1102011300	2006-05-19
Glucose Oxidase Trinder	Glucose Oxidase Trinder	5247	5247	1102011300	2006-05-19
Glucose Oxidase Liquid	Glucose Oxidase Liquid	5248	5248	1102011300	2006-05-19
Glycohemoglobin	Glycohemoglobin	5249	5249	1102011400	2006-05-19
HBDH, Kinetic	HBDH, Kinetic Test	5250	5250	1101011800	2006-05-19
HBDH, Kinetic	HBDH, Kinetic Test	5251	5251	1101011800	2006-05-19
HDL Cholesterol PEG	HDL Cholesterol PEG	5252	5252	1102011500	2006-05-19
Hemoglobin	Hemoglobin	5253	5253	1301700100	2006-05-19
Iron & TIBC	Iron & TIBC	5254	5254	1102011700	2006-05-19
Inorganic Phosphorus Color	Inorganic Phosphorus Color	5255	5255	1103010800	2006-05-19
Inorganic Phosphorus UV	Inorganic Phosphorus UV	5256	5256	1103010800	2006-05-19
LDH-L, Liquid	LDH-L, Liquid	5257	5257	1101011900	2006-05-19
LDH, Kinetic	LDH, Kinetic Test	5258	5258	1101011900	2006-05-19
LDH, Kinetic	LDH, Kinetic Test	5259	5259	1101011900	2006-05-19
LDH, Color Endpoint	LDH, Color End Point Test	5260	5260	1101011900	2006-05-19
Magnesium	Magnesium	5261	5261	1103010700	2006-05-19
CSF/Urine Protein	CSF/Urine Protein	5262	5262	1150900300	2006-05-19
Potassium	Potassium	5263	5263	1103010900	2006-05-19
Sodium	Sodium	5264	5264	1103011000	2006-05-19
Total Lipid	Total Lipid	5265	5265	1102012800	2006-05-19
Total Protein	Total Protein	5266	5266	1102013000	2006-05-19
Triglyceride, GPO	Triglyceride, GPO	5267	5267	1102013100	2006-05-19
Triglyceride, GPO	Triglyceride, GPO	5268	5268	1102013100	2006-05-19



Device name	Description	New Ref number	Old Ref number	EDMS-code	First date of CE-marking
Chemistry	Chemistry				
Triglyceride, GPO, Liquid	Triglyceride, GPO, Liquid	5269	5269	1102013100	2006-05-19
Uric Acid, Color Endpoint	Uric Acid, Color End Point Test	5270	5270	1102013200	2006-05-19
Uric Acid, Color Endpoint	Uric Acid, Color End Point Test	5271	5271	1102013200	2006-05-19
Uric Acid, Liquid	Uric Acid, Liquid	5272	5272	1102013200	2006-05-19

Device name	Description	New Ref number	Old Ref number	EDMS-code	First date of CE-marking
Devices	Devices, tools				
Salicule	Saliva Collector, with filter	5301		51090101	2007-02-01
Salicule	Saliva Collector, no filter	5302		51090101	2007-02-01