

Declaration of Conformity

Manufacturer: Address:	VivaChek Biotech (Hangzhou) Co., Ltd Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China
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PRODUCT NAME	MODEL
VivaDiag™ POCT Analyzer	VIM1000/VIM2000
VivaDiag™ Whole C-Reactive Protein Test Kit	VID01
VivaDiag™ Procalcitonin Test Kit	VID02
VivaDiag™ Cystatin C Test Kit	VID03
VivaDiag™ Serum Amyloid A Protein Test Kit	VID04
VivaDiag™ Interleukin 6 Test Kit	VID05
VivaDiag™ Micro Albuminuria Test Kit	VID06
VivaDiag™ Beta-2 Microglobulin Test Kit	VID07
VivaDiag™ Neutropil Gelatinase-associated Lipocalin Test Kit	VID08
VivaDiag™ Cardiac Troponin I Test Kit	VID09
VivaDiag™ Creatine Kinase-MB Test Kit	VID10
VivaDiag™ D-Dimer Test Kit	VID11
VivaDiag™ Myoglobin Test Kit	VID12
VivaDiag™ Heart Fatty Acid Binding Protein Test Kit	VID13
VivaDiag™ N-terminal Pro-brain Natriuretic Peptide Test Kit	VID14
VivaDiag™ Cardiac Combo (cTnl/CK-MB/MYO) Test Kit	VID15
VivaDiag™ Glycosylated Hemoglobin Test Kit	VID16
VivaDiag™ C-peptide Test Kit	VID17
VivaDiag™ Insulin Test Kit	VID18
VivaDiag™ Beta Human Chorionic Gonadotropin Test Kit	VID19
VivaDiag™ Thyroid Stimulating Hormone Test Kit	VID20
VivaDiag™ Triiodothyronine Test Kit	VID21
VivaDiag™ Thyroxine Test Kit	VID22



VivaDiag™ Luteinising Hormone Test Kit	VID23
VivaDiag™ Prostate Specific Antigen Test Kit	VID24
VivaDiag™ Alpha Fetoprotein Test Kit	VID25
VivaDiag™ Carcino-embryonic Antigen Test Kit	VID26
VivaDiag™ Fecal Occult Blood Test Kit	VID27
VivaDiag™ Ferritin Test Kit	VID28
VivaDiag™ 25-Hydroxyvitamin D3 Test Kit	VID29
VivaDiag™ Anti-Mullerian Hormone Test Kit	VID30
VivaDiag™ Follicle Stimulating Hormone Test Kit	VID31
VivaDiag™ Prolactin Test Kit	VID32
VivaDiag™ Inhibin B Test Kit	VID33
VivaDiag™ Homocysteine Test Kit	VID34
VivaDiag™ Morphine Test Kit	VID37
VivaDiag™ Methamphetamine Test Kit	VID38
VivaDiag™ Ketamine Test Kit	VID39
VivaDiag™ Tetrahydrocannabinol Test Kit	VID40
VivaDiag™ Cocaine Test Kit	VID41
VivaDiag™ MDMA Test Kit	VID42
VivaDiag™ SARS-CoV-2 Ag FIA Test	VID44
VivaDiag™ Cardiac Combo (cTnI/CK-MB) Test Kit	VID45
VivaDiag™ Drug of Abuse Combo (MOR/MET/KET) Test Kit	VID46
VivaDiag™ Whole C-Reactive Protein Control Solution	VIC01
VivaDiag™ Procalcitonin Control Solution	VIC02
VivaDiag™ Cystatin C Control Solution	VIC03
VivaDiag™ Serum Amyloid A Control Solution	VIC04
VivaDiag™ Interleukin 6 Control Solution	VIC05
VivaDiag™ Micro Albuminuria Control Solution	VIC06
VivaDiag™ Beta-2 Microglobulin Control Solution	VIC07
VivaDiag™ Neutropil Gelatinase-associated Lipocalin Control Solution	VIC08
VivaDiag™ Cardiac Troponin I Control Solution	VIC09
VivaDiag™ Creatine Kinase-MB Control Solution	VIC10
VivaDiag™ D-Dimer Control Solution	VIC11
VivaDiag™ Myoglobin Control Solution	VIC12
VivaDiag™ Heart Fatty Acid Binding Protein Control Solution	VIC13
VivaDiag™ N-terminal Pro-brain Natriuretic Peptide Control Solution	VIC14
VivaDiag™ Cardiac Combo (cTnI/CK-MB/MYO) Control Solution	VIC15

VivaDiag™ Glycosylated Hemoglobin Control Solution	VIC16
VivaDiag™ C-peptide Control Solution	VIC17
VivaDiag™ Insulin Control Solution	VIC18
VivaDiag™ Beta Human Chorionic Gonadotropin Control Solution	VIC19
VivaDiag™ Thyroid Stimulating Hormone Control Solution	VIC20
VivaDiag™ Triiodothyronine Control Solution	VIC21
VivaDiag™ Thyroxine Control Solution	VIC22
VivaDiag™ Luteinising Hormone Control Solution	VIC23
VivaDiag™ Prostate Specific Antigen Control Solution	VIC24
VivaDiag™ Alpha Fetoprotein Control Solution	VIC25
VivaDiag™ Carcino-embryonic Antigen Control Solution	VIC26
VivaDiag™ Fecal Occult Blood Control Solution	VIC27
VivaDiag™ Ferritin Control Solution	VIC28
VivaDiag™ Vitamin D Control Solution	VIC29
VivaDiag™ Anti-müllerian Hormone Control Solution	VIC30
VivaDiag™ Follicle-stimulating Hormone Control Solution	VIC31
VivaDiag™ Prolactin Control Solution	VIC32
VivaDiag™ Inhibin B Control Solution	VIC33
VivaDiag™ Homocysteine Control Solution	VIC34
VivaDiag™ Influenza A+B Control Solution	VIC36
VivaDiag™ Morphine Control Solution	VIC37
VivaDiag™ Methamphetamine Control Solution	VIC38
VivaDiag™ Ketamine Control Solution	VIC39
VivaDiag™ Tetrahydrocannabinol Control Solution	VIC40
VivaDiag™ Ketamine Control Solution	VIC41
VivaDiag™ Cardiac Combo (cTnl/CK-MB) Control Solution	VIC45
VivaDiag™ Drug of Abuse Combo (MOR/MET/KET) Control Solution	VIC46

Classification (Article 9, 98/79/EC) : Others

Conformity Assessment procedure: 98/79/EC ANNEX III

We hereby declare that the above mentioned products meet the COUNCIL DIRECTIVE 98/79/EC and applicable Standards. All supporting documentations are retained in the manufacturer and EU representative.

Hangzhou, China, 18th Jan, 2022

Place, Date of issue


Bekki Liu
Regulatory Affairs Department
VivaChek Biotech (Hangzhou) Co., Ltd

