

TABEL / 12.05.2020 – DISPOZITIVE MEDICALE PENTRU DIAGNOSTIC IN VITRO PENTRU COVID-19 INREGISTRATE IN UE

NR CRT	PRODUCATOR	DENUMIRE PRODUS
1	PCL. Inc., Coreea	PCL COVID19 Ag Rapid FIA; PCL COVID19 IgG/IgM Rapid Gold
2	SCREEN ITALIA SRL, Italia	SCREEN TEST COVID-19 - 2019-NCOV IGG/IGM RAPID TEST CASSETTE
3	BIOPLASTIC SOCIETA IN ACCOMANDITA SEMPLICE DI PETRALIA MARIO, Italia	COVID-19 IGG/IGM RAPID TEST
4	Swedice AB, Suedia	COVID-19
5	Roche Molecular Systems, Inc., SUA	SARS-CoV-2 Control Kit
6	Shanghai Kehua Bio-engineering Co., Ltd., China	Diagnostic kit for SARS-CoV-2 IgG Antibody (ELISA)
7	Shanghai Kehua Bio-engineering Co., Ltd., China	Diagnostic kit for SARS-CoV-2 IgM Antibody (ELISA)
8	Shanghai Kehua Bio-engineering Co., Ltd., China	Diagnostic kit for SARS-CoV-2 IgG/IgM Antibody (Colloidal Gold)
9	Shanghai Kehua Bio-engineering Co., Ltd., China	Diagnostic kit for SARS-CoV-2 Nucleic Acid Real Time PCR
10	PCL. Inc., Coreea	PCLMD™ nCoV one step RT-PCR kit
11	BioCore Co.Ltd., Coreea	BioCore 2019-nCoV Real Time PCR Kit: AdvanSure™ COVID-19 real-time RT-PCR
12	QIAGEN GmbH, Germania	QIAstat-Dx Respiratory SARS-CoV-2 Panel
13	BGI EUROPE A/S, Danemarca	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV
14	HANGZHOU ALLTEST BIOTECH CO., LTD., China	AMIINCP-402S -2019-NCOV FIRNGERTIP
15	HANGZHOU ALLTEST BIOTECH CO., LTD., China	2019-NCOV CORONA VIRUS AMI-INCP402
16	INTERMEDICAL S.R.L., Italia	2019-NCOV IGG/IGM
17	Hangzhou Laihe Biotech Co., Ltd., China	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)
18	CORIS BioConcept, Belgia	COVID-19 Ag Respi-Strip
19	Shenzhen Lvshiyuan Biotechnology Co., Ltd., China	COVID-19(2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit
20	M monitor Inc., Coreea	Isopollo® COVID-19 detection kit (real-time); Isopollo® COVID-19 detection kit (premix)
21	GENOBIO PHARMACEUTICAL CO, LTD, China	COVID-19 IGG LATERAL FLOW ASSAY KIT 40 TEST/COVGLFA-01
22	GENOBIO PHARMACEUTICAL CO, LTD, China	COVID-19 IGM LATERAL FLOW ASSAY KIT 40 TEST/COVMLFA-01
23	CLONIT SRL, Italia	QUANTY COVID-19
24	OACP S.R.L., Italia	CORONA VIRUS DISEASE 2019 (COVID-19) NUCLEIC ACID DETECTION KIT
25	A & B PROFESSIONAL INTERNATIONAL SRL, Italia	A&B RAPID TEST COVID-19 IGG/IGM CASSETTA
26	DIASORIN MOLECULAR LLC, SUA	SIMPLEXA COVID-19 POSITIVE CONTROL PACK
27	DIASORIN MOLECULAR LLC, SUA	SIMPLEXA COVID-19 DIRECT
28	ALCO-SERVICE DI CRIPPA ANDREA CRISTIAN, Italia	TEST COVID-19 - 2019-NCOV IGG/IGM RAPID TEST CASSETTE SINGLE USE KIT
29	SENTINEL CH. SPA, Italia	STAT-NAT COVID-19 B
30	SENTINEL CH. SPA, Italia	STAT-NAT COVID-19 HK
31	SCREEN ITALIA SRL, Italia	SCREEN TEST COVID-19 -COVID-19 IGG/IGM RAPID TEST DIPSTICK

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32	AITbiotech Pte. Ltd., Singapore	abTES COVID-19 qPCR I Kit
33	Chaozhou Hybrilio Biochemistry, China	HBRT-COVID-19
34	GenSure Biotech Inc., China	GenSure™ COVID-19 IgG/IgM Rapid Test
35	GenSure Biotech Inc., China	GenSure™ COVID-19 IgM Rapid Test
36	Life Technologies Corporation, SUA	TaqPath™ COVID-19 CE-IVD RT-PCR Kit
37	Autobio Diagnostics Co. Ltd, China	SARS-CoV-2 IgG CLIA Microparticles
38	Autobio Diagnostics Co. Ltd, China	SARS-CoV-2 IgM CLIA Microparticles
39	GUANGZHOU WONDFO BIOTECH CO. LTD, China	SARS-COV-2 ANTIBODY TEST
40	GUANGZHOU WONDFO BIOTECH CO. LTD, China	SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD)
41	GUANGZHOU WONDFO BIOTECH CO. LTD, China	SARS-COV-2 IGM TEST
42	Suzhou Sym-Bio Lifescience Co., Ltd, China	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay
43	Biotech & Biomedicine (Shenyang) Group Ltd., China	Real Time PCR Detection Kit For COVID-19 Coronavirus
44	Biotech & Biomedicine (Shenyang) Group Ltd., China	Colorimetric And Isothermal Detection Kit For COVID-19 Coronavirus
45	Philosys Co Ltd., Coreea	Gmate® COVID-19
46	Osang Healthcare Co., Ltd, Coreea	Gene Finder Covid-19 Plus Real Amp Kit
47	Bioneer Corporation, Coreea	AccuPower® SARS-CoV-2 Real-Time RT-PCR Kit; AccuPower® COVID-19 Real-Time RT-PCR Kit
48	AccuBioTech Co., Ltd., China	ACCU-TELL® COVID-19 IgG/IgM Cassette
49	GenBody Inc., Coreea	GenBody COVID-19 IgM/IgG
50	SD Biosensor, Inc., Coreea	STANDARD Q COVID-19 Ag Control; STANDARD COVID 19 IgM/IgG Control
51	GeneMatrix Inc., Coreea	NeoPlex COVID-19 Detection Kit
52	Wuhan HealthCare Biotechnology Co., Ltd, China	Corona Virus Disease 2019 (COVID-19) Nucleic Acid Detection Kit
53	1drop Inc., Coreea	1copy COVID-19 qPCR Kit; 1copy COVID-19 qPCR Multi Kit
54	SD Biosensor, Inc., Coreea	STANDARD M nCoV Real-Time Detection kit; STANDARD F COVID-19 Ag FIA; STANDARD F COVID 19 IgM/IgG Duo FIA; STANDARD™F COVID-19 IgM/IgG Combo FIA
55	Sugentech, Inc., Coreea	SGTi-flex COVID-19 IgG; SGTi-flex COVID-19 IgM; SGTi-flex COVID-19 IgM/IgG
56	KH Medical Co., Ltd., Coreea	RADI COVID-19 Detection Kit
57	CTK Biotech Inc., SUA	OnSite COVID-19 IgG/IgM Rapid Test; Aria COVID-19 IgG/IgM Rapid Test

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58	MABSKY BIO-TECH CO.,LTD, China	Influenza A virus; Influenza B virus&COVID-19 virus(2019-nCoV) Triple-Detection Kit (Real-Time PCR Method)
59	MABSKY BIO-TECH CO.,LTD, China	COVID-19 virus(2019-nCoV) Triple-Detection Kit (Real-Time PCR Method)
60	MABSKY BIO-TECH CO.,LTD, China	COVID-19 virus(2019-nCoV) Dual-Detection Kit (Real-Time PCR Method)
61	BioMedomics, Inc., SUA	COVID-19 IgM-IgG Rapid Test
62	Beijing Hotgen Biotech Co., Ltd, China	Coronavirus disease (COVID-19) IgM/IgG Antibody Test (Up-converting Phosphor Technology)
63	Beijing Hotgen Biotech Co., Ltd, China	Coronavirus disease (COVID-19) IgM/IgG Antibody Rapid Test (Colloidal Gold)
64	Genomictree, Inc., Coreea	AccuraTect COVID-19 RT-qPCR Kit V1: AccuraDTect™ SARS-CoV-2 RT-qPCR Kit
65	Humasis Co., Ltd., Coreea	Humasis COVID-19 IgG/IgM Test; Humasis COVID-19 IgG/IgM Antibody Test
66	PaxGenBio Co., Ltd., Coreea	PaxView COVID-19 real-time RT-PCR Kit
67	NanoEnTek Inc., Coreea	FREND COVID-19 IgG/IgM Duo
68	CTK Biotech Inc., SUA	Aridia COVID-19 Real-Time PCR Test
69	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD., China	COVID-19(SARS-CoV-2) Antibody Test Kit(Colloidal Gold)
70	Shaanxi Lifegen. Co., Ltd., China	Novel coronavirus (COVID-19) nucleic acid detection kit
71	Beijing Hotgen Biotech Co., Ltd, China	Coronavirus disease (COVID-19) Antibody Test (Enzyme-Linked Immunosorbent Assay)
72	Biomerica, Inc., SUA	COVID-19 IgG/IgM Rapid Test; COVID-19 IgG/IgM Rapid Strip Test
73	Beijing Hotgen Biotech Co., Ltd, China	Coronavirus disease (COVID-19) Nucleic Acid Test Kit (PCR-Fluorescent Probe Method)
74	BeiJing Abace Biology Co., Ltd., China	COVID-19 IgM/IgG Antibody Test Kit (Colloidal Gold Immunochromatography)
75	Chongqing Western Biomedical Technology Co,Ltd., China	Nucleic Acid Detection Kit for Novel Coronavirus (COVID-19) One-Step Taqman qPCR
76	Epitope Diagnostics, Inc., SUA	EDI Novel Coronavirus COVID-19 IgG ELISA Kit; EDI Novel Coronavirus COVID-19 IgM ELISA Kit
77	DIATHEVA S.R.L., Italia	COVID-19 PCR DIATHEVA DETECTION KIT
78	ERGON SUTRAMED S.R.L., Italia	COVID-19 IGG/IGM RAPID TEST CASSETTE
79	BOSTON BIO LAB INC., SUA	COVID-19 Home Test Kit for detection of IgM antibody of SARS-CoV-2
80	BOSTON BIO LAB INC., SUA	COVID-19 Home Test Kit IgG
81	BOSTON BIO LAB INC., SUA	COVID-19 Home Test Kit IgG+IgM
82	Nantong Egens Biotechnology Co., Ltd, China	COVID-19 IgG/IgM Rapid Test Kit
83	Core Technology Co.,Ltd., China	COVID-19 IgM/IgG Ab Test
84	SureScreen Diagnostics, UK	COVID-19 IgG/IgM Rapid Test Cassete (Whole Blood / Serum / Plasma)
85	Healgen Scientific Limited Liability Company, SUA	COVID-19 IgG/IgM Rapid Test Cassete (Whole Blood/Serum/Plasma) – marca Healgen

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86	Changsha Sinocare Inc., China	SARS-CoV-2 IgG Antibody Test Strip – marca SINOCARE
87	Changsha Sinocare Inc., China	SARS-CoV-2 IgM Antibody Test Strip – marca SINOCARE
88	Changsha Sinocare Inc., China	SARS-CoV-2 Antibody Test Strip (Colloidal Gold Method) – marca SINOCARE
89	Abbott Rapid Diagnostics Jena GmbH, Germania	Panbio COVID-19 IgG/IgM Rapid Test Device (Fingerstick Whole Blood/Venous Whole Blood/Serum/Plasma)
90	Guangzhou Darui Biotechnology Co.,Ltd., China	SARS-Cov-2 IgG Antibody Detection Kit (Colloidal Gold); SARS-Cov-2 IgM Antibody Detection Kit (Colloidal Gold)
91	Guangzhou Darui Biotechnology Co.,Ltd., China	SARS-Cov-2 IgM Antibody Detection Kit (ELISA); SARS-Cov-2 IgG Antibody Detection Kit (ELISA)
92	Dirui Industrial Co., Ltd., China	SARS-CoV-2 IgG Antibody Detection Kit (Chemiluminescence Immunoassay)
93	Dirui Industrial Co., Ltd., China	SARS-CoV-2 IgM Antibody Detection Kit (Chemiluminescence Immunoassay)
94	Beijing Jinwofu Bioengineering Technology Co.Ltd., China	Jinwofu® SARS-CoV-2 IgG Antibody Rapid Test
95	Beijing Jinwofu Bioengineering Technology Co.Ltd., China	Jinwofu® SARS-CoV-2 IgM Antibody Rapid Test
96	Beijing Jinwofu Bioengineering Technology Co.Ltd., China	Jinwofu® SARS-CoV-2 IgM/IgG Antibody Rapid Test
97	Beijing Jinwofu Bioengineering Technology Co.Ltd., China	Jinwofu®(SARS-CoV-2) Antigen Rapid Test
98	Biobase Biodustry (Shandong) Co.,Ltd, China	2019-nCOV IgM/IgG Antibody Test Kit (Colloidal Gold)
99	Innovation Biotechnology Co., Ltd.Jiangsu, China	Novel Coronavirus (SARS-CoV-2) IgG/IgM Antibody Test Kit (Immunochromatography)
100	DiaCarta, Inc., SUA	QuantiVirus™ Real-Time PCR Coronavirus (SARS- CoV-2) Detection Test; QuantiVirus™ SARS-CoV-2 Multiplex Detection Test
101	Quidel Corporation, SUA	Lyra® SARS-CoV-2 Assay; Lyra® Direct SARS-CoV-2 Assay
102	VIRAMED Biotech AG, Germania	SARS-CoV-2 ViraChip IgG Test Kit
103	VIRAMED Biotech AG, Germania	SARS-CoV-2 ViraChip IgA Test Kit
104	MIKROGEN GmbH, Germania	ampliCube Coronavirus SARS-CoV-2
105	MIKROGEN GmbH, Germania	recomWell SARS-CoV-2 IgG
106	GENERI BIOTECH s.r.o., Cehia	gb SARS-CoV-2 N (confirmation test)
107	GENERI BIOTECH s.r.o., Cehia	gb SARS-CoV-2 RdRP (confirmation test)
108	gerbion GmbH & Co. KG, Germania	virellaSARS-CoV-2 seqc real time RT-PCR Kit 2.0
109	Roche Diagnostics GmbH, Germania	Elecsys Anti-SARS-CoV-2
110	AniCon Labor GmbH, Germania	Kylt® SARS-CoV-2 Confirmation RTU
111	AniCon Labor GmbH, Germania	Kylt® SARS-CoV-2 Screening RTU
112	HANGZHOU BIOER TECHNOLOGY CO., LTD.	SARS-CoV-2 Nucleic Acid Detection Kit(Fluorescence RT-PCR)
113	Pharmact GmbH, Germania	BelTEST It ! SARS-CoV-2 specific IgM / IgG
114	altona Diagnostics GmbH, Germania	RealStar SARS-CoV-2 RT-PCR Kit 1.0
115	GeneScan Diagnostics, SUA	SARS-CoV-2 IgG/IgM Antibody Rapid Test Kit

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116	Anhui Anke Biotechnology(Group) Co., Ltd., China	SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)
117	ACON Laboratories, Inc., SUA	ACON® SARS-CoV-2 IgG/IgM Rapid Test
118	PlexBio Co., Ltd. , Taiwan – China	IntelliPlex SARS-CoV-2 Detection Kit
119	Advanced Biological Laboratories s.a., Luxemburg	UltraGene Combo2Screen SARS-CoV-2 Assay
120	Vela Diagnostics, Singapore	ViroKey SARS-CoV-2 RT-PCR Test
121	ScheBo Biotech AG, Germania	ScheBo SARS-CoV-2 Quick
122	TATAA Biocenter ab, Suedia	TATAA GrandPerformance SARS-CoV-2 detection kit
123	Jiangsu Superbio Biomedical (Nanjing) Co., Ltd., China	SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)
124	General Biologicals Corporation, Taiwan – China	GB SARS-CoV-2 Real- Time RT-PCR
125	Beijing Lepu Medical Technology Co., Ltd., China	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)
126	NeuMoDx Molecular, Inc., SUA	NeuMoDx™ SARS-CoV-2 Test Strip
127	Seegene Inc., Coreea	Allplex™2019-nCoV Assay; Allplex™ SARS-CoV-2 Assay
128	ERGON SUTRAMED S.R.L., Italia	SARS-COV-2 ANTIBODY TEST
129	Autobio Diagnostics Co. Ltd, China	SARS-CoV-2 Control
130	Autobio Diagnostics Co. Ltd, China	SARS-CoV-2 rRT-PCR
131	Autobio Diagnostics Co. Ltd, China	Anti-SARS-CoV-2 Rapid Test
132	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China	Wantai SARS-CoV-2 Ab Rapid Test
133	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China	Wantai SARS-CoV-2 IgM ELISA
134	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China	Wantai SARS-CoV-2 Ab ELISA
135	Guangzhou Wondfo Biotech Co. Ltd., China	Finecare™ SARS-CoV-2 Antibody Test
136	Guangzhou Wondfo Biotech Co. Ltd., China	Finecare™ SARS-CoV-2 IgM Test
137	Guangzhou Wondfo Biotech Co. Ltd., China	Wondfo SARS-CoV-2 Antibody Test (Lateral Flow method)
138	Foregene Co., Ltd., China	SARS-CoV-2 Nucleic Acid Detection Kit (Multiplex PCR Fluorescent Probe Method)
139	Guangzhou Tebsun Bio-Tech Development Co., LTD., China	SARS-CoV-2 IgM/IgG Antibody Test Kit (Colloidal Gold Immunochromatographic Assay)
140	Guangzhou Tebsun Bio-Tech Development Co., LTD., China	SARS-CoV-2 Nucleic Acid Test
141	Seinda Biomedical Corporation, China	SARS-CoV-2 Antigen Test (CoVisAg)
142	RayBiotech Life, Inc., SUA	Novel Coronavirus (SARS-CoV-2) IgG Antibody Detection Kit (Colloidal Gold Method)
143	RayBiotech Life, Inc., SUA	Novel Coronavirus (SARS-CoV-2) IgM antibody detection kit (colloidal gold method)
144	Procomcure Biotech GmbH, Austria	PhoenixDx SARS-CoV-2 IVD
145	Access Bio, Inc., SUA	CareStart™ COVID-19 IgM/IgG
146	Access Bio, Inc., SUA	CareStart™ COVID-19 MDx RT-PCR
147	HangZhou Lifereal biotechnology CO.,Ltd., China	COVID-19 nucleic acid (RNA) Detection kit (Real-time Fluorescent PCR method)
148	HangZhou Lifereal biotechnology CO.,Ltd., China	COVID-19 nucleic acid (RNA) POCT detection kit (AIGS real-time fluorescent PCR method)

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149	Hangzhou Genesee Biotechnology Co. Ltd., China	COVID-19 IgG/IgM Rapid Test Cassette
150	Cell ID Pte Ltd., Singapore	Smart COVID-19 IgM/IgG RDT
151	DxGen Corp., Coreea	Epithod®616 COVID-19 IgM/IgG Test Kit
152	NewScen Coast Bio-Pharmaceutical Co., Ltd., China	COVID-19 IgG/IgM Rapid Test Cassette
153	Accobiotech SDN BDH, Malaiezia	Acco COVID-19 IgM/IgG
154	Surge Medical Inc., China	COVID-19 IgG/IgM Antibody Assay Kit(Colloidal Gold Method)
155	Joonghun Pharmaceutical Co., Ltd., Coreea	JD COVID-19 qRT-PCR Kit
156	WELLS BIO, INC., Coreea	careGENE™ N-CoV RT-PCR kit; careGENE™ COVID-19 RT-PCR kit; BZ QPCR COVID-19 α kit
157	EuDiPia Co., Ltd., Coreea	EuDx™ COVID-19 Detection Kit
158	Green Cross Medical Science Corporation, Coreea	GENEDIA W COVID-19 IgM/IgG
159	Asan Pharmaceutical Co., Ltd., Coreea	Asan Easy Test® COVID-19 IgG/IgM
160	MPC International S.A., Luxemburg	MEDsan COVID-19 IgM/IgG Rapid Test
161	DIALAB - Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H., Austria	DIAQUICK COVID-19 IgG/IgM Cassette
162	Atlas Link (Beijing) Technology Co., Ltd., China	NOVA Test® COVID-19 IgG/IgM Antibody Test (Colloidal Gold)
163	GeneOne Diagnostic Corporation, Taiwan – China	GeneOne COVID-19 Nucleic Acid Diagnostic Kit
164	Shanghai Liangrun Biomedicine Technology Co.,Ltd., China	Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus COVID-19
165	Zhengzhou Fortune Bioscience Co., Ltd., China	COVID-19 IgG Antibody Rapid Test Kit (Colloidal Gold Immunochromatography Method)
166	Chongqing Western Biomedical Technology Co,Ltd., China	Nucleic Acid Detection Kit for Novel Coronavirus (COVID-19) One-Step Taqman qPCR
167	Shenzhen New Industries Biomedical Engineering Co., Ltd., China	2019-nCov IgM – marca SNIBE
168	Shenzhen New Industries Biomedical Engineering Co., Ltd., China	2019-nCov IgG – marca SNIBE
169	Abbott Molecular Inc, SUA	Abbott RealTime SARS-CoV-2 RT-PCR; Abbott RealTime SARS-CoV-2 Control Kit; Abbott RealTime SARS-CoV-2 Amplification Reagent Kit (9N77)
170	Abbott Ireland Diagnostics Division, Irlanda	SARS-CoV-2 IgG Reagent Kit; SARS-CoV-2 IgG Calibrator Kit; SARS-CoV-2 IgG Control Kit (6R86)
171	AMEDA Labordiagnostik GmbH, Austria	AMP Rapid Test SARS-CoV-2 IgG/IgM
172	VivaChek Biotech (Hangzhou) Co., Ltd., China	VivaDiag COVID-19 IgM/IgG Rapid Test