



REPUBLIC OF BULGARIA

Ministry of Health

Minister of Health

O R D E R

РД-01-623/23.07.2021

for amendment of Order № РД-01-597 / 16.07.2021

Pursuant to Art. 61, para. 2, Art. 63, para. 4, 5 and 11 and Art. 63c of the Health Act, Art. 73 of the Administrative Procedure Code, and in relation to Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic and Council of Ministers Decision № 426 of 26 May 2021 on extending the term of the extraordinary epidemic situation announced by Decision № 325 of the Council of Ministers of 14 May 2020, extended by Decision № 378 of the Council of Ministers of 12 June 2020, Decision № 418 of the Council of Ministers of 25 June 2020, Decision № 482 of the Council of Ministers of 15 July 2020, Decision № 525 of the Council of Ministers of 30 July 2020, Decision № 609 of the Council of Ministers of 23 August 2020, Decision № 673 of the Council of Ministers of 25 September 2020, Decision № 855 of the Council of Ministers of 25 November 2020, Decision № 72 of the Council of Ministers of 26 January 2021 and Decision № 395 of the Council of Ministers of 28 April 2021 and a proposal by the Chief State Health Inspector

O R D E R:

1. I amend Order № РД-01-597 of 16.07.2021 as follows:

a) I amend Annex № 1 to items I, 3 as follows:

„Annex № 1 to item I, 3”

List of countries by color zones, the countries for which there is information about a significant negative change in the epidemic situation and countries with passage on a reciprocal basis

Green zone:

Republic of Austria, Federal Republic of Germany, Republic of Estonia, Iceland, Republic of Lithuania, Republic of Poland, Slovak Republic, Hungary, Republic of Finland, Republic of Croatia, Kingdom of Denmark, Italian Republic, Republic of Slovenia, French Republic, Kingdom of Norway, Republic of San Marino, Vatican City State, Swiss Confederation and the Czech Republic.

Orange zone:

All countries outside the green and the red zone.

Red zone:

Republic of India, People's Republic of Bangladesh, Federal Democratic Republic of Nepal, Myanmar, Kingdom of Bhutan, Democratic Socialist Republic of Sri Lanka, Republic of Maldives, Republic of South Africa, Republic of Botswana, United Republic of Tanzania, Republic of Seychelles, Republic of Seychelles, Republic of Namibia, Republic of Zambia, Republic of Tunisia, Sultanate of Oman, Malaysia, Turkmenistan, Republic of Tajikistan, Kyrgyz Republic, Mongolia, Republic of Colombia, Republic of Chile, Eastern Republic of Uruguay, Republic of Argentina, Federative Republic of Brazil, Republic of Paraguay, Multinational State of Bolivia, Republic of Peru, Republic of Suriname, Republic of Panama, Republic of Costa Rica, Republic of Guatemala, Belize, Republic of El Salvador, Republic of Cuba and Dominican Republic, Republic of Cyprus, United Kingdom of Great Britain and Northern Ireland, the Kingdom of Spain, Fiji, the Emirate of Kuwait, the Republic of Malta, the Principality of Andorra, the Kingdom of the Netherlands and Georgia.

Countries with which the Republic of Bulgaria has reached an agreement on free passage on a reciprocal basis of their citizens and persons with the status of permanent, long-term or continuous residence and members of their families, on arrival from the other country: Romania.

Countries for which there is information about a significant negative change in the epidemic situation and the application of specific control measures for the persons arriving from them:

Russian Federation, Portuguese Republic and Islamic Republic of Pakistan - arrivals are permitted on the country upon presentation of a valid EU digital COVID certificate for testing or a similar document, showing a negative result from from a polymerase chain reaction (PCR) test for COVID-19 conducted up to 72 hours before entry into the country as from the date of the sampling entered in the document. For Bulgarian citizens and persons with the status of permanent, long-term or continuous residence on the territory of the Republic of Bulgaria and the members of their families, items 4.2.2 and 4.2.3. shall apply.“

b) I amend Annex № 2 to item I, 4.1.2 as follows:

„Annex № 2 to item I, 4.1.2”

Test name	Test manufacturer
COVID-VIRO® Rapid antigen test COVID-19	AAZ-LMB
Panbio™ COVID-19 Ag Rapid Test	Abbott Rapid Diagnostics
SARS-CoV-2 Antigen Rapid Test	Acon Biotech (Hangzhou) Co., Ltd
Flowflex SARS-CoV-2 Antigen Rapid Test	ACON Laboratories, Inc.
AESKU.RAPID SARS-CoV-2	AESKU.DIAGNOSTICS GmbH & Co, KG
TestNOW® - COVID-19 Antigen Test	Affimedix Inc.
AMP Rapid Test SARSCoV-2 Ag	AMEDA Labordiagnostik GmbH
Rapid COVID-19 Antigen-Test (colloidal Gold)	Anbio (Xiamen) Biotechnology Co., Ltd
COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)	Anhui Deep Blue Medical Technology Co., Ltd
COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) – Nasal swab	Anhui Deep Blue Medical Technology Co., Ltd
mariPOC SARS-CoV-2	ArcDia International Ltd
mariPOC Respi+	ArcDia International Oy Ltd
mariPOC Quick Flu+	ArcDia International Oy Ltd
Artron COVID-19 Antigen Test	Artron Laboratories Inc.
Asan Easy Test COVID-19 Ag	Asan Pharmaceutical Co., Ltd
ECOTEST COVID-19 Antigen Rapid Test Device	Assure Tech. (Hangzhou) Co., Ltd.
NOVA Test ® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	Atlas Link Technology Co. Ltd.
Ksmart® SARS-COV2 Antigen Rapid Test	Avalun
COVID-19 Antigen Rapid Test	AXIOM Gesellschaft für Diagnostica und

	Biochemica mbH
COVID-19 Antigen Rapid Test Device	Azure Biotech, Inc.
BD Veritor™ System for Rapid Detection of SARS CoV 2	Becton Dickinson
Novel Coronavirus 2019nCoV Antigen Test (Colloidal Gold)	Beijing Hotgen Biotech Co., Ltd
Novel Coronavirus (SARSCoV-2) Antigen Rapid Test Kit	Beijing Jinwofu Bioengineering Technology Co.,Ltd.
SARS-CoV-2 Antigen Rapid Test Kit	Beijing Lepu Medical Technology Co., Ltd
Wantai SARS-CoV-2 Ag Rapid Test (FIA)	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd
Wantai SARS-CoV-2 Ag Rapid Test (colloidal gold)	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd
Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab)	Biomerica Inc.
NowCheck COVID-19 Ag Test	BIONOTE
CORONAVIRUS AG RAPID TEST CASSETTE	BIO-RAD
BIOSYNEX COVID-19 Ag BSS	BIOSYNEX S.A.
BIOSYNEX COVID-19 Ag+ BSS	BIOSYNEX SA
SARS-CoV-2 Antigen Test Kit (colloidal gold method)	BIOTEKE CORPORATION (WUXI) CO., LTD
Rapid Response COVID-19 Antigen Rapid Test	BTNX Inc
CerTest SARS-CoV-2 Card test	CerTest Biotec
Coretests COVID-19 Ag Test	Core Technology Co., Ltd
OnSite COVID-19 Ag Rapid Test	CTK Biotech, Inc
Test Rapid Covid-19 Antigen (tampon nazofaringian)	DDS DIAGNOSTIC
DIAQUICK COVID -19 Ag Cassette	DIALAB GmbH
Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	Edinburgh Genetics Limited
EBS SARS-CoV-2 Ag Rapid Test	Eurobio Scientific
ESPLINE SARS-CoV-2	Fujirebio
Genbody COVID-19 Ag Test	GenBody Inc
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Genrui Biotech Inc
GenSure COVID-19 Antigen Rapid Test Kit	GenSure Biotech Inc
SARS-CoV-2 Antigen (Colloidal Gold)	Getein Biotech, Inc
One Step Test for SARSCoV-2 Antigen (Colloidal Gold)	Getein Biotech, Inc.
SARS-CoV-2 Antigen Kit (Colloidal Gold)	Goldsite Diagnostic Inc.
GENEDIA W COVID-19 Ag	Green Cross Medical Science Corp.

2019-nCoV Antigen Test Kit (colloidal gold method)	Guangdong Hecin Scientific, Inc.
COVID-2019-nCoV Ag Rapid Test Detection Kit (ImmunoChromatography)	Guangdong Longsee Biomedical Co., Ltd.
COVID-19 Ag Test Kit	Guangdong Wesail Biotech Co. Ltd
V-CHEK, 2019-nCoV Ag Rapid Test Kit (ImmunoChromatography)	Guangzhou Decheng Biotechnology CO., Ltd
Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Guangzhou Wondfo Biotech Co., Ltd
COVID-19 Antigen Rapid Test Device (Colloidal Gold)	Hangzhou Lysun Biotechnology Co. Ltd
COVID-19 Antigen Rapid Test	Hangzhou AllTest Biotech Co., Ltd
COVID-19 Antigen Rapid Test Cassette	Hangzhou Clongene Biotech Co., Ltd
Covid-19 Antigen Rapid Test Kit	Hangzhou Clongene Biotech Co., Ltd.
COVID-19/Influenza A+B Antigen Combo Rapid Test	Hangzhou Clongene Biotech Co., Ltd.
Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)	Hangzhou Immuno Biotech Co., Ltd
SARS-CoV2 Antigen Rapid Test	Hangzhou Immuno Biotech Co., Ltd
LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co.
Covid-19 Antigen Test Cassette	Hangzhou Testsea Biotechnology Co., Ltd.
Coronavirus Ag Rapid Test Cassette	Healgen Scientific
Humasis COVID-19 Ag Test	Humasis
Novel Corona Virus (SARSCoV-2) Ag Rapid Test Kit	Jiangsu Bioperfectus Technologies Co., Ltd.
COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	Jiangsu Diagnostics Biotechnology Co., Ltd
SARS-CoV-2 antigen Test Kit (LFIA)	Jiangsu Medomics medical technology Co.,Ltd.
COVID-19 Rapid Antigen Test (Colloidal Gold)	Joinstar Biomedical Technology Co. Ltd
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	JOYSBIO (Tianjin) Biotechnology Co., Ltd.
SARS-CoV-2 Antigen Rapid Test Kit	Labnovation Technologies Inc.
PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Lumigenex (Suzhou) Co., Ltd
QuickProfile™ COVID-19 Antigen Test	LumiQuick Diagnostics Inc.
LumiraDx SARS-CoV-2 Ag Test	LumiraDX
MEDsan SARS-CoV-2 Antigen Rapid Test	MEDsan GmbH
SARS-CoV-2 Antigen Rapid Test Cassette	Merlin Biomedical (Xiamen) Co., Ltd.

MEXACARE COVID-19 Antigen Rapid Test	MEXACARE GmbH
mö-screen Corona Antigen Test	möLab
Rapid SARS-CoV-2 Antigen Test Card	MP Biomedicals
NADAL COVID -19 Ag +Influenza A/B Test	Nal von minden GmbH
NADAL COVID -19 Ag Test	Nal von minden GmbH
FREND COVID-19 Ag	NanoEntek
NanoRepro SARS-CoV-2 Antigen Rapid Test	NanoRepro AG
COVID-19 Antigen Detection Kit	New Gene (Hangzhou) Bioengineering Co., Ltd.
SARS-CoV-2 Antigen Rapid Test	Novatech
CAT	Oncosem Onkolojik Sistemler San. ve Tic. A.S.
PCL COVID19 Ag Rapid FIA	PCL Inc.
PCL COVID19 Ag Gold	PCL Inc.
SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)	PerGrande Bio Tech Development Co., Ltd.
Exdia COVI-19 Ag	Precision Biosensor Inc.
Rapid Test Ag 2019-nCov	Prognosis Biotech
SARS-CoV-2 Antigen Rapid Test (Immunochromatography)	Qingdao Hightop Biotech Co. Ltd
Sofia SARS Antigen FIA	Quidel Corporation
SARS-CoV-2 Rapid Antigen Test	Roche (SD BIOSENSOR)
SARS-CoV-2 Rapid Antigen Test Nasal	Roche (SD BIOSENSOR)
COVID-19 Antigen Rapid Test Kit (Swab)	Safecare Biotech (Hangzhou) Co. Ltd
Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19)	Safecare Biotech (Hangzhou) Co. Ltd
ScheBo SARS CoV-2 Quick Antigen	ScheBo Biotech AG
STANDARD Q COVID-19 Ag Test Nasal	SD Biosensor Inc
STANDARD F COVID-19 Ag FIA	SD BIOSENSOR Inc.
STANDARD Q COVID-19 Ag Test	SD BIOSENSOR Inc.
V-Chek SARS-CoV-2 Ag Rapid Test Kit (Colloidal Gold)	SGA Medikal
V-Chek SARS-CoV-2 Rapid Ag Test (colloidal gold)	SGA Medikal
SARS-CoV-2 Antigen Test Kit	Shenzen Ultra-Diagnostics Biotec Co., Ltd
Green Spring SARS-CoV-2 Antigen-Rapid test-Set	Shenzhen Lvshiyuan Biotechnology Co., Ltd.
SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	Shenzhen Microprofit Biotech Co., Ltd

SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	Shenzhen Watmind Medical Co., Ltd
SARS-CoV-2 Ag Diagnostic Test Kit (Immunofluorescence)	Shenzhen Watmind Medical Co., Ltd
Zhenrui ®COVID-19 Antigen Test Cassette	Shenzhen Zhenrui Biotech Co., Ltd
CLINITEST Rapid COVID-19 Antigen Test	Siemens Healthineers
SGTi-flex COVID-19 Ag	Sugentech, Inc.
TODA CORONADIAG Ag	TODA PHARMA
SARS-CoV-2 Antigen Rapid Test Kit	Triplex International Biosciences Co., Ltd
SARS-CoV-2 Antigen Rapid Test Kit	Triplex International Biosciences Co., Ltd, China
RapidFor SARS-CoV-2 Rapid Ag Test	Vitrosens Biotechnology Co., Ltd
VivaDiag Pro SARS-CoV-2 Ag Rapid Test	VivaChek Biotech (Hangzhou) Co., Ltd.
COVID-19 (SARS-CoV-2) Antigen-Test Kit	Wuhan EasyDiagnosis Biomedicine Co., Ltd.
SARS-CoV-2 Antigen Assay Kit (Immunochromatography)	Wuhan Life Origin Biotech Joint Stock Co., Ltd.
SARS-CoV-2 Antigen Rapid Test Kit	Wuhan UNscience Biotechnology Co., Ltd.
COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	Xiamen AmonMed Biotechnology Co., Ltd
Rapid SARS-CoV-2 Antigen Test Card	Xiamen Boson Biotech Co. Ltd
SARS-CoV-2 Antigen Rapid Test	Xiamen Wiz Biotech Co., Ltd
SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	Xiamen Wiz Biotech Co., Ltd
AndLucky COVID-19 Antigen Rapid Test	Zhejiang Anji Saianfu Biotech Co., Ltd
reOpenTest COVID-19 Antigen Rapid Test	Zhejiang Anji Saianfu Biotech Co., Ltd
Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co., Ltd
COVID-19 Antigen Detection Kit (Colloidal Gold)	Zhuhai Lituo Biotechnology Co., Ltd.

2. The Order enters into force on July 26, 2021.

3. The Order ought to be published on the website of the Ministry of Health.

The order is subject to appeal within one month from the publication on the website of the Ministry of Health, in front of the relevant administrative court under the Administrative Procedure Code.

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DR. STOICHO KATSAROV

Minister of Health