EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security

EU health preparedness:

A common list of COVID-19 rapid antigen tests and a common standardised set of data to be included in COVID-19 test result certificates

Agreed by the Health Security Committee

This document was agreed by the HSC on 17 February 2021

Annex I

Common list of COVID-19 rapid antigen tests

A first update was agreed by the HSC on 10 May 2021; A second update was agreed by the HSC on 16 June 2021; A third update was agreed by the HSC on 7 July 2021; A fourth update was agreed by the HSC on 14 July 2021; A fifth update was agreed by the HSC on 23 July 2021.

IMPORTANT: A (interim) grace period of 8 weeks applies whenever updates are made to Annex I, the common list of COVID-19 rapid antigen tests

Annex II

Common standardised data set to be included in COVID-19 test result certificates

An update to Annex II was agreed by the HSC on 19 March 2021

ANNEX I: Common list of rapid antigen tests[10]

As agreed by Member States on 23 July 2021

***Disclaimer**: This list was agreed by the HSC based on a proposal by the Technical Working Group on COVID-19 Diagnostic Tests. Experts participating in the Technical Working Group strongly recommend that use of rapid antigen tests is primarily intended for preliminary testing for SARS-CoV-2 infection in symptomatic patients, and note that rapid antigen tests should in particular be used in the specific contexts and circumstances referred to by the Commission Recommendation (EU) 2020/1743 of 18 November 2020 and the technical guidance by ECDC on 19 November 2020. The content of the common list is based on the clinical performance data and information that is available at this moment in time. The common list of rapid antigen tests does not include rapid antigen self-tests nor rapid antigen tests that are based on samples other than those collected from nasal, oropharyngeal or nasopharyngeal specimens. Updates to the common list are based on the criteria as described in Council Recommendation 2021/C 24/01 as well as the additional criteria and definitions agreed by the Technical Working Group on 29 June 2021. Discussions on criteria and definitions will continue during summer 2021, also taking into consideration the work carried out by the In Vitro Diagnostics Working Group of the Medical Device Coordination Group[9] on guidance on the performance of COVID-19 tests in the context of CE-marking and common specifications under Article 9 of Regulation (EU) 2017/746.*

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Completed validation studies	MS currently validating	Device ID # *in JRC database*[11]	Included in Common list of RATs as of:
AAZ-LMB	COVID-VIRO® Rapid antigen test COVID-19	Yes	96.6% sensitivity 100% specificity	**BE:** 96.6% sensitivity, 100% specificity, NP swab **FR:** >95%% sensitivity, 100% specificity **SI:** 96.6% sensitivity, 100% specificity, NP swab		BE, FR, SI	CH	FR CH		1833	10 May 2021
Abbott Rapid Diagnostics	Panbio™ COVID-19 Ag Rapid Test	Yes	91.4% sensitivity 99.8% specificity NP swab (Ct ≤ 33) 98.1% sensitivity 99.8% specificity Nasal swab (Ct ≤ 33)	**BE**[6]: Small-scale head-to-head comparison of 5 RATs in Belgian hospital lab. Panbio overall sensitivity (Ct range 14,6 – 35,5): 45/57 samples (79%). Sensitivity for Ct≤25: 17/18 samples. Overall specificity 100%. **DE:** 91.4% sensitivity 99.8% specificity, NP swab; 98.1% sensitivity, 99,8 specificity, Nasal swab	DE (10 Dec 2020) 1108 samples, NP swab Clinical sensitivities: - Days ≤ 7: 90.8%; - Ct ≤ 33: 88.3%; - Ct ≤ 25: 95.8%; Clinical specificity: 99.9% CH (10 Dec 2020) 535 samples, NP swab	AT, BE, BG, CY, CZ, DE[2], DK, EE, EL, ES, FR[1], HR, IT, LT, LV, MT, NL[5], PL, PT, RO, SE, SK	CH, ME, MK, NO, UK, UA	DE[2], ES, FI, NL[5], PT CH, NO	CY, ES, HR, HU, IE, LU, SE	1232	17 February 2021

[10] This is the list of rapid antigen tests as referred to in Article 3 of the 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, OJ L 211, 15.6.2021, p. 1–22.

[11] See: https://covid-19-diagnostics.jrc.ec.europa.eu/.

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Completed validation studies	MS currently validating	Device ID # *in JRC database*[11]	Included in Common list of RATs as of:
BIOTEKE CORPORATION (WUXI) CO., LTD	SARS-CoV-2 Antigen Test Kit (colloidal gold method)	Yes	96.49 % sensitivity 99.28 % specificity OP/NP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct25) + Manufacturer specificity: 99.28%		DE[2]		DE[2]		2067	14 July 2021
Biotical Health S.L.U.BIOTICAL HEALTH S.L.U	biotical SARS-CoV-2 Ag Card	Yes	Sensitivity: 96%, Specificity: 99% NP swab	**BE:** Validation study 1: sensitivity 91.7% for Ct≤25; Validation study 2: 94% for Ct≤25. Manufacturer specificity: 99%		BE		BE		Yes (2013)	23 July 2021
Boditech Med Inc	AFIAS COVID-19 Ag	Yes	Sensitivity: 91.7%, Specificity: 98.7% NP swab	**NL:** Independent field study in mild symptomatic (n= 427); overall sensitivity: 81.1% (106 PCR+), Ct <30: 96.4% (85 PCR+), PCR on NP+OP, Target antigen = nucleoprotein		FR, NL		NL		Yes (1989)	23 July 2021
BTNX Inc	Rapid Response COVID-19 Antigen Rapid Test	Yes	90.2% sensitivity 100% specificity NP swab, NP swab, OP swab	**DE:** 94.55% sensitivity, 100% specificity		AT, DE[2], ES, SI		DE[2]		1236	10 May 2021
CerTest Biotec	CerTest SARS-CoV-2 Card test	Yes	92.9% sensitivity 99.6% specificity NP swab	**ES:** Ct ≤ 25, sensitivity: 94,0%; sensitivity for samples within the first 5 days after symptom onset: 84,8%		ES, PT, SI		DE[2], ES		1173	17 February 2021
Core Technology Co., Ltd	Coretests COVID-19 Ag Test	Yes	98.1% sensitivity 99.6% specificity NP swab	**DE:** 98.1% sensitivity, 99.6% specificity		AT, DE[2], RO		DE[2]		1919	10 May 2021
CTK Biotech, Inc	OnSite COVID-19 Ag Rapid Test	Yes	Clinical Sensitivity: 92.3 % Clinical Specificity: 100 % Nasal, NP swab	**ES:** 219 samples; Nasal swab - Clinical sensitivity 86% (90%: Ct <30) Specificity: 100% (Method B) **DK:** 107 samples; Nasal swab - clinical sensitivity 86%; (from asymptomatic and mild symptomatic individuals), Clinical specificity: 100%	*To start*	DK		DK, ES		1581	7 July 2021
DDS DIAGNOSTIC	Test Rapid Covid-19 Antigen (tampon nazofaringian)	Yes	98.77% sensitivity 99.03% specificity Nasal swab	**RO:** Meets the minimum performance requirements.		RO		RO China	RO	1225	10 May 2021
DIALAB GmbH	DIAQUICK COVID -19 Ag Cassette	Yes		**BE:** Z20401CE: 93.2% sensitivity, 100% specificity, NP swab		AT, BE, DE[2]		DE[2]		1375	10 May 2021