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

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 I: Common list of rapid antigen tests[10]

As agreed by Member States on 16 June 2201

***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	In JRC database (Device ID #)[11]
…	…									
Nal von minden GmbH	**NADAL COVID -19 Ag Test**	Yes	97.6% sensitivity 99.9% specificity Nasal swab	**BE: 97.6% sensitivity, 99.9% specificity, NP/OP swab** **DE:97.6% sensitivity, 99.9% specificity** **SI: 97.6% sensitivity, 99.9% specificity, NP/OP swab**	CH (26 April 2021) 462 samples, NP swab Clinical sensitivities: - Days < 7: 88.5%; - Ct < 33: 92.4%; - Ct < 25: 97.8%; Clinical specificity: 99.2%	AT, BE, CY DE[2], FR, PT, SI		DE, FR, CHINA	HR, SKUP	Yes (1162)
…	…									