

ANNEX III: Common list of COVID-19 laboratory based antigenic assays

As agreed by Member States on 20 October 2021

Manufacturer	RAT commercial name	Device ID # ²³	Clinical performance <i>As reported by independent validation studies</i>	Clinical performance <i>Data by manufacturer</i>	EU Member States using in practice	Other countries using in practice	Completed validation studies	SARS-CoV-2 Target protein	Included in EU common list since:
DIASORIN	LIAISON SARS-CoV-2 Ag assay	1960	<i>Prospective clinical field studies</i>		BE, CZ, FR, IT, NL		BE, FR, IT, NL	Nucleo-capsid protein	20 October 2021
			<p>BE: Independent prospective study (random selection), symptomatic and asymptomatic (n=414, PCR positive = 204, PCR negative = 210), NP swab; sensitivity Ct<35: 73.4%, sensitivity Ct<25: 96.4%; specificity: 100%</p> <p>FR: Independent prospective study, symptomatic and asymptomatic (n=378, PCR positive = 46), NP swab; overall sensitivity: 84.8%, sensitivity Ct=<25 100%; specificity: 99.4%</p> <p>IT: Independent prospective study, asymptomatic (n=1075, PCR positive = 23), NP swab; sensitivity Ct=<30 90.5%; specificity: 99.8%</p> <p>NL : Independent field study, mainly symptomatic individuals (n=980, PCR positive n=98), NP+OP swab; sensitivity overall 82.7%, sensitivity Ct<30: 91.9%; specificity overall: 99.1%.</p>	<p>Nasal Swab: Sensitivity: 99/101 (98.0%, 95% CI: 93.1 – 99.5%). Specificity: 210/211 (99.5%, 95% CI: 97.4 – 99.9%).</p> <p>NP Swabs: Sensitivity: 108/109 (99.1%, 95% CI: 95.0 – 99.8%). Specificity: 295/299 (98.7%, 95% CI: 96.6 – 99.5%).</p>					
Roche Diagnostics GmbH	Elecsys® SARS-CoV-2 Antigen	2156	<i>Prospective clinical field study</i>		DE ^[2] , EE, PL		DE ^[2]	Nucleo-capsid protein	20 October 2021
			<p>DE: Total N: 3139 (2747 negative, 392 positive) Germany participated in the validation. Roche coordinated and performed partially the data analysis. Relative specificity overall 99.9%; relative sensitivity (n=390) overall 92.5% (CT<26).</p>	<p>Sensitivity: NP/OP: 94.5 % (95% CI: 90.4-97.2); Nasal swabs: 96.8% (95% CI: 88.8-99.6%) Specificity: 99.9% (95 % CI: 99.6-100%)</p>					

²³ As registered in and used by the JRC database, see: <https://covid-19-diagnostics.jrc.ec.europa.eu/>.