Evaluation of SARS-CoV-2 Antigen tests[1]

The evaluation[1] was planned by the Paul-Ehrlich-Institute (PEI, Germany) and conducted by the Robert-Koch-Institute (RKI, Germany), the national reference laboratory for coronaviruses (Institute for virology, Charité – university medicine Berlin, Germany), institute for microbiology of the German Federal armed forces (IMB, Munich, Germany) and the PEI, itself, in order to evaluate the state of the art concerning sensitivity. Specificities were not evaluated.

Test name	Supplier	Number of laboratories	Sensitivity rate in %[2]			
			Viral culture[3] %	Ct <25 %	Ct 25-30 %	Ct > 30 %
Panbio™ COVID-19 Ag rapid test	Abbott	5	95,6	96,7	45,2	0,0
RIDA®QUICK SARS-CoV-2 Antigen	R-Biopharm AG	3	96,3	98,2	71,0	7,4
SARS-CoV-2 Rapid Antigen Test	Roche	4	94,4	97,2	55,4	11,1
NADAL® COVID-19 Ag rapid test	Nal van minden	2	77,8	77,8	6,5	0,0
Antigen Test SARS CoV-2 (Prototype)	Dräger	2	77,8	80,6	15,2	0,0
Standard™ F COVID-19 Ag FIA	SD Biosensor, Inc.	2	100	100	45,7	0,0
Standard™ Q COVID-19 Ag Test	SD Biosensor, Inc.	2	100	94,4	54,4	5,5
NowCheck COVID-19 Ag Test	Bionote	2	100	100	67,4	5,5
Clinitest COVID-19-rapid test	Siemens Healthineers	2	100	100	71,7	16,6

In order to identify potentially infectious individuals the sensitivity was assessed with samples that contained infectious SARS-CoV-2 in viral culture. On this basis, 7 out of 9 antigen rapid tests showed a sensitivity > 80 %. With regard on samples, containing high viral concentrations (Ct < 25) 8 out of 9 antigen rapid tests showed a sensitivity of > 80 %.

Thus, the analyzed rapid tests might be suitable to identify infectious individuals with the evaluated sensitivities.

[1] First evaluation of SARS-CoV-2 Antigen Tests, Paul-Ehrlich-Institut, 06.11.2020
[2] Per cent positive samples in each test for the corresponding Ct-value range
[3] Per cent positive samples in each test over all Ct-values, in which virus could be grown in cell culture