

From: SANTE C3 HSC
Sent: mercredi 26 mai 2021 13:50
To: SANTE C3 HSC
Subject: URGENT - Availability of RATs in JRC database

Dear members of the Health Security Committee,
Dear colleagues,

As discussed at the HSC meeting today, it is of great importance that **all the rapid antigen tests included in the HSC agreed RAT common list are also available in the JRC COVID-19 In Vitro Diagnostic Devices and Test Methods Database**. As the information encoded in the JRC database will be linked to the future EU Digital COVID-19 Certificate, it is key that relevant manufacturers provide the JRC with details of their product. This will allow for the creation of the future digital COVID-19 test certificates to be carried by travellers and that can be based on the results of rapid antigen tests included in the HSC agreed list.

More specifically, there are currently **12 rapid antigen tests** of which the HSC agreed that they should be included in the RAT common list, but which are not in the JRC database. You will find the details below.

We would like to urge you, and in particular those countries that are using these RATs in practice, to ensure that the companies will provide JRC with the necessary details so that their device can be included and thus used for the creation of the future EU Digital COVID-19 test certificates. Manufacturers can provide the necessary information here: [EUSurvey - Survey \(europa.eu\)](https://europa.eu/eusurvey/survey).

To ensure the swift and timely continuation of the development of the EU Digital COVID-19 Certificate, **companies are required to submit the relevant data by 31 May the latest.**

Kind regards,
HSC Secretariat

12 rapid antigen tests of the HSC agreed RAT list that are currently not included in the JRC database:

	Manufacturer	Commercial name	Countries that are using the RATs
1	AESKU.DIAGNOSTICS GmbH & Co, KG	AESKU.RAPID SARS-CoV-2	AT, DE, SI
2	Affimedix	TestNOW® - COVID-19 Antigen	DE
3	AXIOM Gesellschaft für Diagnostica und Biochemica mbH	COVID-19 Antigen Rapid Test	DE
4	Core Technology Co., Ltd	Canea Covid-19 Antigen Rapid Test	DE
5	Hangzhou Immuno BiotechCo., Ltd	SARS-CoV2 Antigen Rapid Test	AT, DE
6	Hangzhou Lysun Biotechnology Co., Ltd.	COVID-19 antigen Rapid Test Device (Colloidal	DE, CH

		Gold)	
7	Lumigenex (Suzhou) Co., Ltd	PocRoc SARS-Cov-2 Antigen Schnellnachweiskit (Gold kolloidal)	DE
8	nal von minden GmbH	NADAL COVID -19 Ag +Influenza A/B Test	DE
9	PerGrande Biotech Development Co., Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic assay)	AT, DE
10	Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2 Antigen-Rapid test-Set	DE
11	VivaChek Biotech (Hangzhou) Co., Ltd.	Vivadiag Pro SARS-CoV-2 Ag Rapid Test	AT
12	Wuhan EasyDiagnosis Biomedicine Co., Ltd.	Antigen-Testkit for COVID-19 (SARS-Cov-2)	DE