

From: SANTE TWG RAT
Sent: lundi 12 juillet 2021 11:23
To: [REDACTED]@aemps.es
Cc: [REDACTED]@sanidad.gob.es; JRC COVID DIAGNOSTICS
Subject: RE: Validation Study of rapid antigen test BioRad-Spain

Dear [REDACTED],

Thank you for your email and proposal. Please note that, as a first step for a test to be considered for inclusion, the manufacturer needs to make sure the device in question is registered in the COVID-19 In Vitro Diagnostic Devices and Test Methods Database, which is hosted by the JRC. By registering, the device will be linked to a specific Device ID, which is mandatory for possible inclusion the RAT common list.

For more information, please see here at the bottom of the page under 'contribute', 'submit your device': [COVID-19 In Vitro Diagnostic Devices and Test Methods Database | COVID-19 In Vitro Diagnostic Devices and Test Methods Database \(europa.eu\)](#).

More information about the process can also be found here: [Technical working group on COVID-19 diagnostic tests | Public Health \(europa.eu\)](#)

If the information will still be provided today, the test will be reviewed by the HSC technical expert working group before the summer break. If the information is submitted after today, the test will be reviewed in September.

Best regards,

TWG Secretariat

From: [REDACTED]@aemps.es <[REDACTED]@aemps.es>
Sent: Monday, July 5, 2021 4:03 PM
To: SANTE TWG RAT <SANTE-TWG-RAT@ec.europa.eu>; JRC COVID DIAGNOSTICS <JRC-COVID-DIAGNOSTICS@ec.europa.eu>
Cc: [REDACTED]@sanidad.gob.es
Subject: Validation Study of rapid antigen test BioRad-Spain

Dear colleagues,

As commented in previous meetings, Spain would like to propose the Rapid antigen test "Bio Rad" to be included in the common list. This test has been validated by "Instituto Carlos III", in Spain.

We are not sure about the procedure to follow for Member states to present a candidate test, so that we uploaded the study in Circa, and we are also sending it to you.

Please, contact us if you need further information or we should follow a different procedure to send the document.

Thanks

Regards,

[Redacted]

Area de Control de mercado de Productos Sanitarios-*In Vitro*
Departamento de Productos Sanitarios

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