From: @sanidad.gob.es

Sent: vendredi 17 septembre 2021 18:08

To: SANTE C3 HSC

Subject: RE: For review and action: EU common list on RAT

No comments from Spain

Have a nice W-E

De: <u>SANTE-C3-HSC@ec.europa.eu</u> [mailto:SANTE-C3-HSC@ec.europa.eu]

Enviado el: jueves, 16 de septiembre de 2021 9:21

Para: SANTE-C3-HSC@ec.europa.eu

Asunto: For review and action: EU common list on RAT

Dear members of the Health Security Committee, Dear colleagues,

Concerning the work carried out by the HSC Technical Working Group on COVID-19 diagnostic tests, please find attached two documents that require your review/action:

- Revised criteria/definitions/considerations related to the EU common list Based on your input to last week's survey as well as further discussions held at the TWG meeting yesterday, this document was further amended. Please let us know by Monday 12:00 if you have any comments, otherwise the TWG will consider them agreed and start using them as of Tue 21 September for the next review of possible new tests to be included in the EU common list.
- 2. RATs currently included in the EU common list As part of the revised criteria, it is key for the TWG to understand what type of evaluation study was carried out: a prospective field study or a retrospective in vitro study. However, for many of the RATs included in the common list, the details on the study designs are unknown. We have indicated this in the second attachment. For the majority of these cases, it concerns RATs that were included by the HSC earlier this year. If relevant, we therefore urge you to please get in touch with your national expert participating in the TWG, and to provide him/her with the necessary documentation of the evaluation study of the RAT that was put forward by you for inclusion. In case this information remains missing, these tests will be put forward for removal of the list as the experts won't be able to conduct the necessary assessment nor conclude whether the criteria are met.

Kind regards, HSC Secretariat

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