

From: [REDACTED]@sanidad.gob.es
Sent: vendredi 15 octobre 2021 15:26
To: SANTE C3 HSC
Subject: RE: FOR REVIEW: Proposal for 6th update of RAT common list – DL 18/10 at 12:00

We agree with the document



SPAIN

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

Enviado el: jueves, 14 de octubre de 2021 17:56

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

Asunto: FOR REVIEW: Proposal for 6th update of RAT common list – DL 18/10 at 12:00

Dear members of the Health Security Committee,
Dear colleagues,

Please find enclosed the proposal of the Technical Working Group on COVID-19 diagnostic devices, for the 6th update of the EU common list on rapid antigen tests. You will find the proposal both in track changes indicating what has changed since the last update as well as the clean version.

In summary, the document includes the following changes:

- **Updated criteria, definitions and considerations**, as agreed by the TWG on 21 September (and as already reviewed by you earlier).
- Based on a review of over 150 proposals received during the summer time, **a proposal to include 20 new rapid antigen tests in the list** – these proposals were assessed against the new criteria.
- The rapid antigen tests already included in the list were also reviewed and further details and information on their performance and in particular the evaluation studies conducted were added by the experts. Based on their review of the current list, the TWG suggests to **remove 2 rapid antigen tests**. No independent validation studies could be identified for these tests (they were included earlier this year based on manufacturer data).
- Note that the TWG came to the conclusion that the majority of the rapid antigen tests already included in the common list meet the new criteria. However, for some the new thresholds are not met, but these will not be removed at this stage as the new criteria will apply to these tests as of May 2022.
- **A proposal for a new grace period**: until the end of the year, a grace period of 8 weeks will apply, and as of 2022 a grace period of 4 weeks will be implemented.
- **A new annex (Annex III) setting out a common list of lab-based antigenic assays** (e.g. ELISA and automated tests) that meet the new criteria and definitions agreed by the TWG on 21 September.

Please have a careful look at the proposal for the 6th update of the document, and let the HSC Secretariat know by **Monday 18 October, 12:00** whether you have any comments. If no feedback is received, the document will be considered agreed by the HSC and published on the same day.

Finally, as you will see in the document, some of the rapid antigen tests that were already included in the list require further investigation by the countries/country experts. We ask in particular the following MS to pay attention to the action points included: AT, BE, DE, FI, RO, SE. Note that these action points should be addressed as part of the next (seventh) update of the RAT common list (and don't require feedback by Monday).

Kind regards,
HSC Secretariat

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