To: 5.1.2e @ec.europa.eu'[5.1.2e @ec.europa.eu]
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(5.1.2e)[5.1.2e @minvws.nl]
From: 5.1.2e)
Sent: Thur 10/15/2020 9:32:00 AM
Subject: RE: Kind reminder: Results rapid antigen test survey + Response ECDCto questions RRA
Received: Thur 10/15/2020 9:32:00 AM

Dear 5.1.2e

Please find our answers to your questions on rapid antigen testing below.

1. What elements should be in an aligned EU approach to the use of rapid antigen tests? E.g. should the HSC develop and agree on a common position?

   In principle, NL is in favor of an aligned EU approach for the use of rapid antigen tests and is therefore in favor of reaching a common position on this matter. However, at this moment NL is still deciding what elements are important to consider for such an aligned EU approach. We will share further information with HSC on this matter when available.

2. Which antigen test should be considered for a Joint Procurement , and what are the minimum thresholds of performance?

   In general, NL is interested in the possibility of considering a Joint Procurement for rapid antigen tests. However, at this moment NL has not yet decided on a position on what specific antigen test should be recommended / selected for a JP. According to NL, important thresholds of performance for selecting a specific antigen test consist of the following:

Manufacturer

- *Company has right of free sale from country of manufacture*
- *Manufactured under quality management system (e.g. ISO 13485)*
- *Has CE/Doc of conformity*
- *Instructions for Use are finalized and available*
- *Manufacturer has demonstrated experience manufacturing RDTs at scale (millions/month)*
- *Manufacturer makes other RDTs that have stringent regulatory authorization*
- *Manufacturer has significant global sales and distribution capacity, including in LMICs*

Test characteristics

- *Has been shown through spiking studies not to cross react with common human coronaviruses*
- *Meets TPP minimal performance criteria (≥80% sensitivity and ≥97% specificity)*
- *Ideally has data from independent studies demonstrating this performance*
- *Ideally has data showing performance in patients with high versus low viral burden*

Ease of use and access

- *Kit contains all materials (except timer, PPE, etc.) necessary to collect and process sample, run the test, and interpret*
- *Predicted shelf life greater than 12 months, ideally 18 months*
- *Storage temperature minimum 28 degrees C*
- *Ideally reader is available to standardize result readout*
- *Result can be read in ≤30 minutes from sample application*
- *Requires only biohazard and not chemical risk disposal*
- *Low cost of price compared to RT-PCR*

Van: 5.1.2e @ec.europa.eu < 5.1.2e @ec.europa.eu>
Verzonden: dinsdag 13 oktober 2020 11:45

Aan: 5.1.2e @ec.europa.eu
Onderwerp: Kind reminder: Results rapid antigen test survey + Response ECDC to questions RRA

Dear members of the Health Security Committee,
Dear colleagues,

Thanks to those of you who provided us with answers to the two questions we circulated last week on rapid antigen tests. In case you haven't yet replied, could you please provide us with your feedback by **Thursday 15 October 12:00**? We strongly encourage you to share your views with us on these two matters as it will be valuable information to have for our discussions at the next HSC meeting.

1. What elements should be in an aligned EU approach to the use of rapid antigen tests? E.g. should the HSC develop and agree on a common position?
2. Which antigen test should be considered for a Joint Procurement , and what are the minimum thresholds of performance?

Thank you and kind regards,

5.1.2e