To: 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e [5.1.2e @rivm.nl]
From: 5.1.2e)
Sent: Wed 11/11/2020 1:38:22 PM
Subject: FW: Validation results of rapid antigen tests DE
Received: Wed 11/11/2020 1:38:43 PM
Anlage_1_Tabelle_Evaluierungsergebnisse_SARS-CoV-2_Antigen-Tests_(Extern....pdf

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Van: 5.1.2e @ec.europa.eu
Verzonden: woensdag 11 november 2020 14:38:06 (UTC+01:00) Amsterdam, Berlijn, Bern, Rome, Stockholm, Wenen
Aan: 5.1.2e @ec.europa.eu
Onderwerp: Validation results of rapid antigen tests DE

Dear Members of the Health Security Committee,
Dear colleagues,

Below you will find the information on the results of the validation of the rapid antigen tests, shared by the DE HSC members, for your information.

Kind regards,
HSC Secretariat

Dear collegues,

please share these results with all HSC members oft he validation oft he rapid antigen tests announced a couple of weeks ago:

The Annex (Table 1) contains the results of the evaluation of SARS-CoV-2 antigen tests for dissemination. The evaluation was carried out jointly by the Robert Koch Institute (RKI), the national Consiliary Laboratory for Coronaviras (Institut für Virologie der Charité – Universitätsmedizin Berlin), the Bundeswehr Institute for Microbiology (IMB) Munich and the Paul Ehrlich Institute (PEI). The participating laboratories have been contacted with regard to the item "consideration of any confidentiality agreements with manufacturers or other concerns about publication". The RKI agrees to the disclosure of the results (Table 1), the other laboratories have not expressed any concerns or confidentiality agreements with the producers.

It should be noted that the tests were selected on the basis of the tests available at the beginning of the evaluation (end of September) in order to assess the state of the art with regard to sensitivity. Specificity wasn't experimentally searched here. As a result, minimum criteria for sensitivity, specificity and potential cross-reactivity/interference were published. This allows manufacturers to submit a request for inclusion in the "list of antigen tests for the direct detection of pathogens of the coronavirus SARS-CoV-2" of the BfArM (https://antigentest.bfarm.de/ords/antigen/r/antigentests-auf-sars-cov-2/liste-der-antigentests?session=13269987983065&tz=1:00) on the basis of their data.

Details of the evaluated tests, tests and evaluation of the results can be found in Table 1:

• 50 respiratory samples from routine diagnostics were compiled by the RKI as an evaluation panel. With the PCR method used at the RKI laboratory samples were defined of high viral load (CT < 25) and the virus propagation in cell culture examined as a possible correlation to potential infectivity. Reference is made to the who Guideline "Antigen detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays: interim guidance, 11 September 2020" (https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays).

• the above mentioned 50 samples were sent to the participating laboratories, where they were tested comparatively with the respective antigen rapid tests. In order to ensure reproducability, the tests in Table 1 were carried out in at least two different laboratories. Tests that have so far only been validated by one laboratory have not been taken into account in this evaluation.

The results are as follows:

• for the intended use of SARS-CoV-2 antigen tests to identify potentially infectious persons, the sensitivity of the antigen tests was determined in the samples containing infectious SARS-CoV-2 virus in virus propagation in cell culture. On this basis, 7 out of 9 of the antigen rapid tests examined showed sensitivity of > 80%, two tests showed sensitivity of 77,8%.

• with regard to high virus concentrations (CT < 25), 8 out of 9 tests showed sensitivity of > 80% and one tested sensitivity of 77,6%.

Conclusion:
Assuming a correlation between virus reproduction in cell culture and the potential infectivity of individuals, the antigen rapid tests in Table 1 may be suitable for detecting SARS-CoV-2 infected persons with the evaluated sensitivity.