Evaluation Records (Partially)

Pass the evaluation by PEI of Germany

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

26.03.2021

Comparative evaluation of the sensitivities of SARS-CoV-2 antigen rapid tests

Aim
Comparison of different antigen rapid tests with using identical sample material

Material
Pools from nasopharyngeal and oropharyngeal swabs.

Dry swabs were included in PBS; moist swabs were already included in the transport media of various compositions. Pools are random mixtures obtained from up to 10 samples of comparable CT values diluted 1:10 in negative samples in PBS. The CT values of a pool were determined by means of different PCR assays, and the putative number of RNA copies calculated with the aid of the INSTAND standards. In the case of the PCRs used, a CT value of 25 corresponds to around 10^5 RNA copies/mL. 18 samples each were analysed with CT<25, 23 samples with CT between 25 and 30, and 9 samples with CT>30. The replication of the virus in cell culture was determined as a possible correlate for infectiousness as another characteristic of the samples.

Method
The pools were aliquoted, frozen, shipped, and thawed for evaluation of the tests. For each test, 50 µL of the pool were analysed using the components of the test provided, e.g. swabs. Laboratories participating in the comparative evaluation included the Robert Koch-Institut, the Paul-Ehrlich-Institut, the reference laboratory for coronaviruses (Charité), and the Institute for Microbiology of the German Army (Bundeswehr).

Summary
This comparative evaluation of a large number of SARS-CoV-2 rapid antigen tests (point of care tests; POCT) of different designs and manufacturers with the same sample set allows an overview of the current state of art regarding sensitivity. The results do not allow any conclusions regarding specificity of the tests.

Those POCTs which have up to now been included in the evaluation and have been assessed as reflecting the current state of the art are listed in the table below. Other tests, which were assessed as not reflecting the state of the art were deleted from the list of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). This comparative evaluation is constantly continued, and the table is amended accordingly.

You should be aware that this comparative evaluation can only cover a random sample of the SARS-CoV-2 rapid antigen tests listed by the BfArM, thus eligible for refunding, and that few other products could not (yet) be taken into account, despite the interests on the part of the manufacturers/distributors.

Contact
Email: sarscov2ivd@pei

Paul-Ehrlich-Institut
Paul-Ehrlich-Str. 51-59
63225 Langen, Germany

www.pei.de

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Name of Test	Manufacturer (Distributor)
Covid-19-Antigen-Test kit	New Gene (Hangzhou) Bioengineering Co., Ltd.