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Stellen für Medizinprodukte in Deutschland

Minimum clinical study parameters for Covid-19 Antigen Self-testing devices

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Disclaimer: since there is no clear guidance available for the setup of layman studies on SARS-COV2 Antigen self-testing devices, this information is provided to manage our expectation. Final decision on study acceptance is made case by case.

Layman study

- Study plan as well as Study report is required
- A Layman study must address the full process, incl. sample collection and device read-out
- At this stage, the only accepted sample collection method is anterior nasal. Other methods might be acceptable if supporting data is available.
- Focus must be the usability of the device, incl. interpretation of the Instructions for Use (main: test method) and result interpretation. The use of usability standard EN 62366 is expected to be applied.
- Indicated age, intended users and ethnic background need to be reflected in the study population
- Study size: minimum of 100 participants; should include min. of 20 positive cases; symptomatic patients (within 7 days after onset of symptoms) preferred to be included!
- User verification requirements defined in various self-testing related standards shall be used, e.g. EN 13612, EN 13532, EN ISO 18113-4, relevant aspects of EN ISO 15223 (non-comprehensive list)

Performance evaluation

- Performance evaluation: please consider criteria in published guidance's by WHO/ ECDC / Paul-Ehrlich Institute
- Comparison to current gold standard (PCR) required (part of performance evaluation and/or layman study)
- Acc. to ECDC criteria, the performance studies must include at least 100 positive cases
- Performance evaluation must address common mutants (e. g. "UK" mutant B.1.1.7, "South Africa mutant B.1.351, "Brasil" mutant P.1)

Instructions for Use

- Clear and detailed description of sample collection process required, including device read-out

- Clear advice (incl. warnings) to layman how to deal with the result obtained (EN ISO 18113-4 to be considered)

If relevant publications on the used SARS-COV2 self-testing device are available, please submit them with your application.

References

Reference to BfArM page "Antigen tests for SARS-CoV-2":

- https://www.bfarm.de/EN/MedicalDevices/AntigenTests/_node.html

Public references for study design:

- https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
- https://www.ecdc.europa.eu/sites/default/files/documents/Options-use-of-rapid-antigen-tests-for-COVID-19_0.pdf
- https://www.finddx.org/wp-content/uploads/2020/04/20200421-COVID-Ag-RDT-Evaluation-Synopsis.pdf
- https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays
- SARS-CoV-2 patient self-testing with an antigen-detecting rapid test: a head-to-head comparison with professional testing | medRxiv
- https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en

Contact

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