STUDY PROTOCOL

Evaluation of SARS-CoV-2 Rapid Antigen Test: increasing testing capacity in screening of SARS-CoV-2

(SARA)

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Rationale: Good and rapid diagnostics are essential for the treatment and control of COVID-19. The current testing regimes relies on active case finding of COVID-19 infection using real-time reverse transcriptase PCR (RT-PCR). RT-PCR is highly sensitive and specific with results obtained within 24 hours. However, control of the pandemic has required countries to drastically scale up their testing capacities in the first wave of the COVID-19 pandemic. Nonetheless the capacity is not enough as the current testing regimes takes at least 24-48 hours from sample to result and this time increases in high prevalent regions.
As such there is an increasing need and demand for rapid test currently being marketed to be used. Reliable rapid diagnostic tests could reduce the pressure on laboratories, GGD and expand testing capacities.
The aim of this protocol is to perform clinical evaluation of several promising Rapid Antigen tests (RATs) against the standard molecular diagnostic assay RT-PCR directly in the field within the GGD COVID19 test lanes.
Objective: Primary objective is to determine the diagnostic performance on sensitivity and specificity of the RAT compared to RT-PCR and usability at GGD test lanes . Secondary objectives are to determine the analytical and diagnostic performance of sensitivity and specificity compared to RT-PCR stratified by viral load/Ct values, disease stage, asymptomatic and severity of symptoms, sample type, prevalence of SARS-CoV-2 in population tested, age and sex.
Study design: Prospective clinical evaluation study and lab based evaluation.
Study population: We aim to include cases visiting GGD test lanes for COVID-19 testing by RT-PCR within the study period and who are willing to participate in the study through informed consent. The sample size is based on the RT-PCR test result prevalence of the GGD test lane (%*100 positive cases and 2x %*100 negative cases). For the lab based evaluation we to include 1500 samples.
Main study parameters/endpoints: Diagnostics and analytical performance of assays on sensitivity and specificity.
Study period and time line: The study period is 2 -4 weeks and depends on the prevalence of the test line.