

ASPHER STATEMENT ON THE COVID-19 TESTING

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https://www.aspher.org/download/421/aspher_statement_on_the_covid-19_testing.pdf

A COVID-19 Testing Decision Tree is provided with the Statement

For an in depth report on the state of the knowledge on COVID-19 Testing, please see Pinto da Costa J, Barros H, Middleton J, et al. COVID-19 testing: A reflection on test accuracy in the real world. ASPHER (2020). https://www.aspher.org/download/420/covid-19_testing_a_reflection_on_test_accuracy_in_the_real_world.pdf

Testing is essential to understand the dynamics of COVID-19 in the population, to plan preventive measures, and to provide the basis for appropriate therapeutic measures. After the identification of the SARS-CoV-2 virus and the clinical definition of COVID-19, there was a rapid development of diagnostic and screening tools. Their accuracy needs to be assessed carefully as the interpretation of results could have profound impacts on individual and public health decision-making. We reviewed the information available on the performance of existing tests to identify the virus (molecular tests) or its immunological expression (serological tests). The major findings and concerns are highlighted below:

Molecular tests for clinical cases and contact tracing

1. Molecular tests - reverse transcription-polymerase chain reaction (RT-PCR) - are essential to confirm a COVID-19 case – to trace contacts, to isolate, and subsequently, to confirm viral clearance, as decisions based on clinical resolution do not seem to match the viral clearance from testing;
2. A meta-analysis cited in this report estimated the pooled sensitivity to RT-PCR as 89% (95%CI: 81-94%);
3. This should lead us to be cautious about the proportion of reported false negatives. The performance of RT-PCR tests, whether for diagnosis or screening,

is a very important concern. False positive results will lead only to a degree of inconvenience for the individuals who have positive results. However, a large number of individuals with false negative results allowed back into general society, or into health and social care, could have a considerable impact and the opportunity for the spread of the virus into susceptible individuals.

4. In the peak period of the pandemic passing through communities, mass testing and contact tracing may not be practicable, and the advice to individuals will be the same regardless of a test result, namely self-isolation.
5. However, there will be a place for reintroduction of testing and contact tracing as numbers reduce, such that countries are looking to reduce lockdown and isolation procedures, and sufficient staffing resources and test kits permit.

Serological tests for case confirmation and advice for contacts and key workers

6. Serological tests are a potential tool that can be used in large scale surveillance efforts to estimate the prevalence of the population ever exposed to the virus, which is expected to be much higher than those diagnosed at any one moment.
7. The presence of antibodies for SARS-CoV-2 does not exclude that the individual may remain infectious due to recent infection, thus, clinical and epidemiological history should also be considered in relation to serological testing;
8. The reliability of serological tests needs to be checked and further development of serological tests is needed. For example, if we are to pursue the idea of an “immunity passport” – this will rely critically on clear evidence of long-lasting immunity;

Serological testing for whole populations

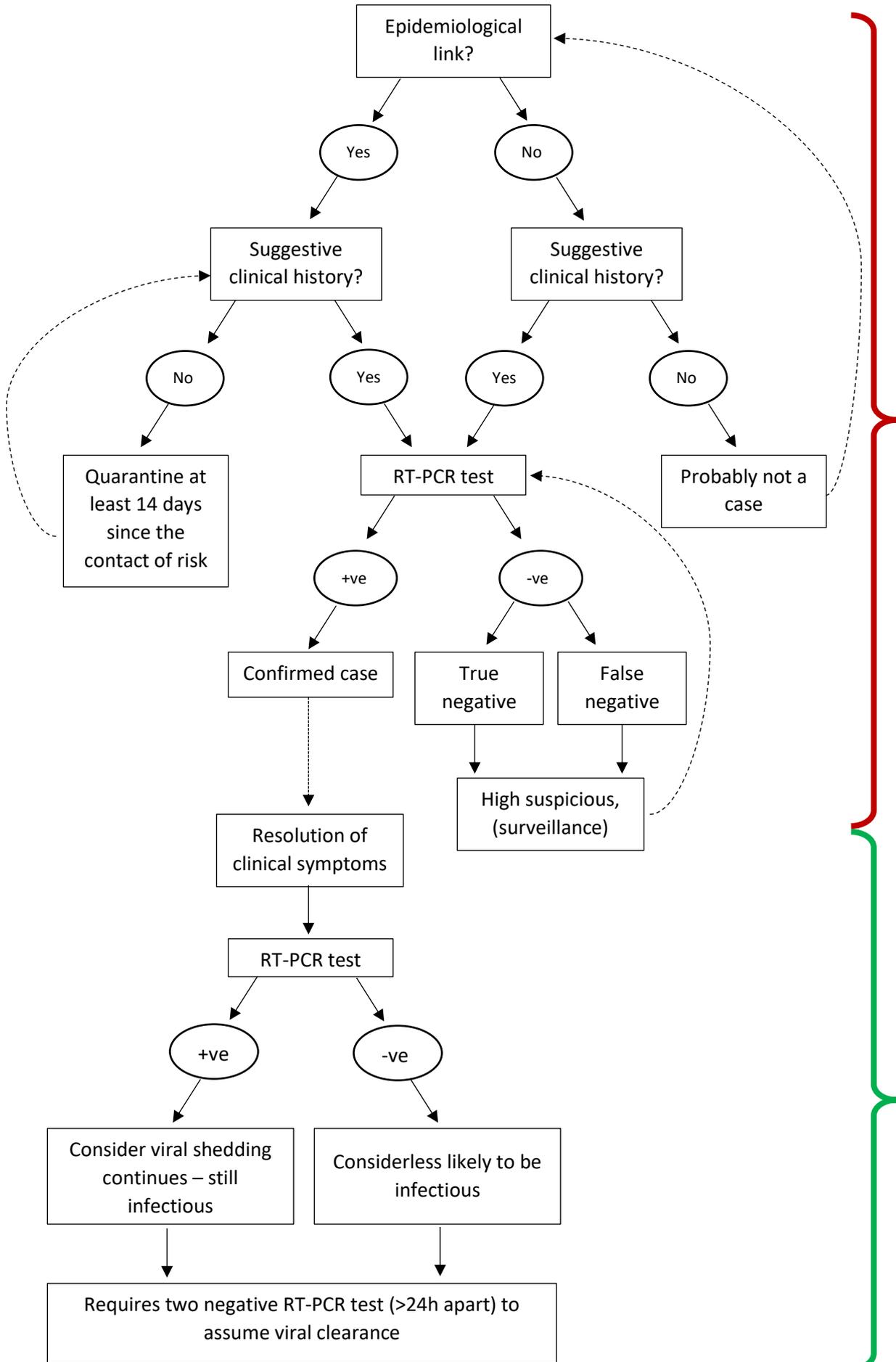
9. Interpretation of test results must be careful and cautious, whether for individuals or whole populations;
 10. The positive predictive value is the proportion of all positive tests which are true positive cases. This figure is more reliable when there is a high prevalence of virus circulating in the community. However, as we test more people, we will find
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large numbers of false positive results, even if the test is thought to have a high specificity. Our estimates of how much virus there is in communities will be very difficult. *We do not know if the high figures being quoted in some studies represent a high level of asymptomatic infections or a high level of false positive tests.*

The assessment of false positives becomes especially important in this situation - as an overestimate of the degree of a previous infection could allow relaxation of controls too soon.

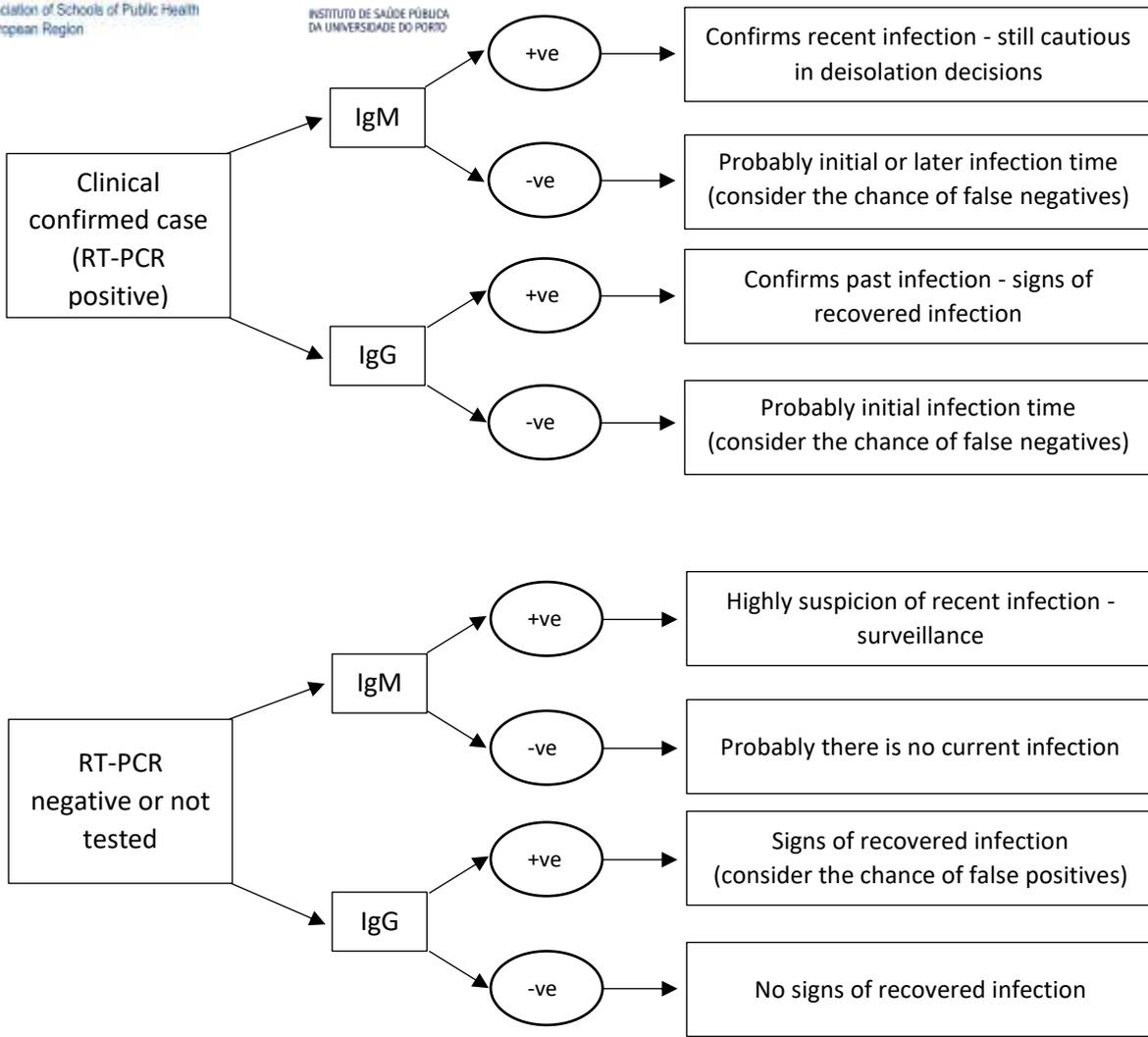
11. An assessment of the extent of spread would be very important in assessing the level of immunity in the population, and the likely impact of relaxing physical distancing and other lockdown measures.
12. An international consensus on what the population parameters are when the relaxation from lockdown might start would be desirable.
13. Testing alone is not a panacea. Testing must always be considered as part of the range of public health, non-pharmaceutical measures available to respond to the current pandemic;
14. A major effort is needed to transparently communicate to the public the issues of testing effectiveness. The public needs and deserves to understand the issues of testing effectiveness and efficiency including what is meant by sensitivity, specificity, and predictive values.

ASPHER calls on the Faculties and Research Centers throughout Europe to contribute to fill the knowledge gaps that have been identified in relating to COVID-19 testing. Much work is already underway and with new information becoming rapidly available. ASPHER will work to keep a bibliography of recent resources at: <https://www.aspher.org/aspher-statement-covid-19-testing.html>

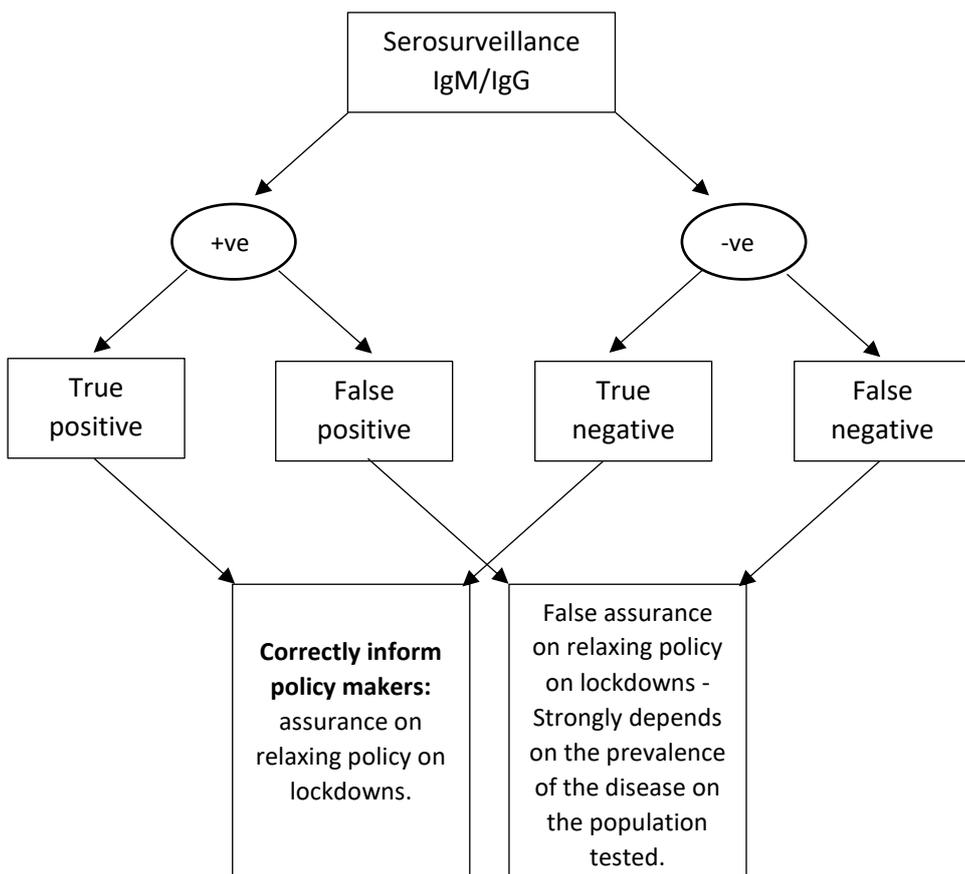


Clinical diagnosis (RT-PCR)

COVID-19 confirmed case discharge



Clinical Follow-up: serological testing (individual approach)



Serological testing (population approach) - seroprevalence