

## Performance evaluation of SARS-CoV-2 antigen tests

January 2021

Biomex GmbH can carry out the necessary tests for the performance evaluation of a SARS-CoV-2 antigen test according to the "*Minimum criteria for Rapid SARS-CoV-2 Antigen Tests in the sense of §1 Abs. 1 Satz 1 TestVO: Rapid Antigen Tests*" of the *Paul-Ehrlich-Institut (PEI)* dated 04.12.2020 and summarizes the results in a report.

<b># 1 Validation: Diagnostic sensitivity/specificity, cross reactivity, interferences</b>
<b>Diagnostic sensitivity</b> <ul style="list-style-type: none"><li>- 100 samples from individuals with Covid-19 symptoms The swabs were collected as dry swabs after onset of symptoms in the early symptomatic phase and were stored at &lt;-20°C until tested. → examination in parallel with a diagn. PCR and the rapid antigen test</li></ul>
<b>Diagnostic specificity</b> <ul style="list-style-type: none"><li>- 100 samples from asymptomatic individuals without specific exposure risk. The dry swabs swabs were stored at &lt;-20°C until tested. Clarification of possible reactive samples by PCR</li></ul>
<b>Cross reactivity</b> <ul style="list-style-type: none"><li>- Analysis of samples with high concentrations of related human coronaviruses: human coronavirus 229E, human coronavirus OC43, human coronavirus NL63, MERS coronavirus</li></ul>
<b>Interference</b> <ul style="list-style-type: none"><li>- Examination of pathogen-positive samples in which the pathogen can cause analogous symptoms: Influenza A, B; RSV</li></ul>
<b>#2 Final report</b>
<b>Preparation of a final report</b>

### Important – please note:

- the projects will commence upon confirmation by Biomex and at a mutually agreed time
- we will reserve a dedicated validation slot for you
- the delivery of the test devices 2 weeks prior to test start and additional extraction buffer (150 mL) in order to test identical samples in PCR and the Ag-test is requested

The this not a binding offer.

If you have any questions, please do not hesitate to contact us.

Best regards  
**BIOMEX GmbH**

Tom Dillig  
*International Sales*