



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

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To the Editor,
Emerging Microbes & Infections

Date 1 September 2020
Subject Submission manuscript 'Validation and clinical
evaluation of a SARS-CoV-2 Surrogate Virus
Neutralization Test (sVNT)'

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Enclosure(s)
none

Dear Editor,

Herewith we submit a manuscript for your consideration as an original research article entitled "Validation and clinical evaluation of a SARS-CoV-2 Surrogate Virus Neutralization Test (sVNT)" by B. Meyer *et al.* for publication in *Emerging Microbes & Infections*. We confirm that this work is original and has not been published elsewhere, nor is it currently under consideration for publication elsewhere. We have no conflicts of interest to disclose.

Cell-based virus neutralization tests are the Gold Standard for detection of SARS-CoV-2 specific antibodies and represent a valuable assay to test for the presence of functional antibodies in vaccine and protective immunity related research. However, such in-house tests have several major draw-backs for a broad and efficient implementation such as the need for a Biosafety level 3 laboratory, the need for highly skilled laboratory scientists and the complexity of standardization across laboratories.

This manuscript describes an extensive, independent, two-centre evaluation of the robustness, specificity and sensitivity of the first commercial immune-assay that indirectly and semi-quantitatively measures the neutralizing functionality of SARS-CoV-2 antibodies while overcoming the above limitations. The assay was evaluated against conventional cell culture-based wildtype SARS-CoV-2 and VSV-based pseudo-type neutralization assays.

We observed that the surrogate assay can be used as an additional assay to determine the immune status of COVID-19 infected or vaccinated individuals and in cohort studies to confirm results of more routine immuno-assays like IgG, IgM and/or IgA ELISAs and CLIAs. However, the value of the surrogate test as functional assay in patient management, biosafety management, vaccine and immunity studies needs to be assessed for the specific context of use.

We believe this manuscript presents valuable data of interest to the readers of *Emerging Microbes and Infections*. We are looking forward to your response.

Sincerely yours, also on behalf of (10)(2e) and the co-authors,

(10)(2e)



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