

## ***Statement of concern***

# **Possible false-positive HIV test results in persons vaccinated against Sars-CoV-2 virus?**

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### **Abstract**

During the development of a vaccine to protect against the Sars-CoV-2 virus, it became apparent that the targeted agent could lead to false positive results in the usual tests for HIV1/2 antibodies. The project was subsequently terminated and the topic disappeared from the attention of science and the media. Thanks to access to anonymized patient data through our international network and case reports within our own reporting system for unusual events, we have come to the hypothesis that this "Australian effect" can also occur with other Sars-CoV-2 vaccines, albeit to a much lesser extent. In individual cases, however, this can have dramatic consequences. For this reason, we are publishing a hypothesis, contrary to our usual conventions. In no way do we wish to minimize the willingness to get vaccinated, nor do we wish to reproach any pharmaceutical company. Nevertheless, it is important to present the facts as they appear to us for discussion and to avoid adverse consequences should such an effect actually materialize in individual cases.

## General considerations

It is almost certain that there are hitherto unexplained peripheral overlaps between Sars-CoV-2 and HIV types 1 and 2.<sup>1,2,5,14</sup> These are not conspiracy theories, but scientific facts of yet poorly understood clinical relevance. As a pars pro toto, note the work of Salih and colleagues (2021) as well as Tan and colleagues (2020). Salih's team states, as one of several, "Similarity between HIV and SARS-CoV-2 spike proteins can lead to antibody cross-reactivities, yielding false-positive results on immunoassay screening tests."<sup>1</sup> Also others<sup>12</sup>, among them 'Nature online' warned that a "HIV protein fragment" in the context of Sars-CoV-2's spike protein could lead to HIV 'false positives'.<sup>5</sup> Assuming that this effect would be limited to the spike protein and the antibodies caused by the virus itself would be preposterous, since the goal of most vaccines against Sars-CoV-2 is to stimulate the body to produce Sars-CoV-2 spike proteins (and the corresponding antibodies) itself.<sup>3</sup> As a consequence, it is reasonable to hypothesize that the proteins and/or antibodies produced due to the vaccines have a similar effect. As we shall see HIV false positives is most likely even a more significant issue with vaccine induced biological elements; certainly not in all vaccinated individuals, but in a small subgroup, which still has to be investigated and defined in more detail. This is also indicated by the failed attempt to successfully market a vaccine against Sars-CoV-2 in Australia. The entire project failed due to false-positive HIV test results.<sup>4,5</sup> An observation for which we have no explanation or even a hypothesis is why this above mentioned effect seems to occur almost exclusively in vaccinated-only, N-protein negative patients. The results of Salih (2021) and Tan (2020) might therefore just describe the tip of an iceberg.<sup>1,2,5</sup>

## Real world implications

Our team became aware of the possibility of false positive HIV tests (all but HIV PCR) in individuals vaccinated against Sars-CoV-2 when a laboratory technician attempted suicide. The reason: five months after his second vaccination against Sars-CoV-2 (being negative for Sars-CoV-2 nucleocapsid antibodies at all times) his HIV antibody tests as well as the usual confirmatory HIV tests yielded positive results. Only multiple controls by means of PCR in various centers of competence showed that the human HI-virus (all HIV subtypes) was and is not detectable in this patient. After such cases became more frequent in our international network, we asked for documentation and reporting. Result: there seems to be a genuine effect, although rather small in magnitude. However, when it comes to HIV and the associated consequences, each individual case is worth taking a closer look at.

## What now?

Our observations and individual case reports should be the impetus for a large-scale study to estimate the extent of the observed effect on the general population. Until then, the PCR technique is a method that should be used in "odd" cases of positive HIV standard antibody tests even if all known confirmatory tests come also back as positive. For example, when individuals with no risk profile test positive for HIV antibodies on a standard and/or confirmatory test, at least three PCR tests within a year should be mandatory. Repeated PCR testing does not cause any harm, but can at best prevent harm. Since testing with PCR does not physically burden the patient in any way, the recommendation for this form of testing should currently be made very generously.

## Conclusion

Based on reasonable suspicion, a small proportion of patients vaccinated against Sars-CoV-2 may experience false-positive HIV antibody test results (including in all known confirmatory tests). However, this does not affect direct HIV detection by PCR technology. The indication for confirmation of a positive HIV antibody test by PCR testing should be made generously in HIV-positive individuals without a risk profile, despite the high cost of HIV PCR testing. Our observation of individual cases and the cited papers should in no way jeopardize vaccination campaigns against Sars-CoV-2. However, the risk we presented should be handled cautiously and transparently. There is no reason for any form of panic. However, a thorough study by a neutral institution is imperative, in our opinion, to safely counteract HIV misdiagnoses on a large scale, especially as this appears to be a long-term effect, if confirmed.<sup>6,7,8,9</sup>

## Conflicts of interest

none

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