Salvagene GROUP

Business Unit: SARS-CoV-2 Task Force
Keynote: #73

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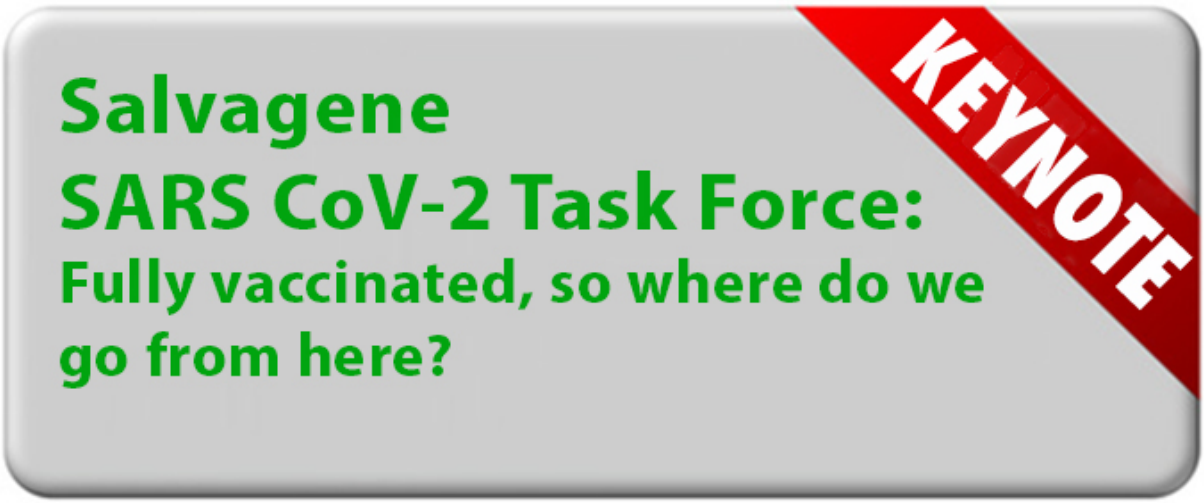

Dear Premium Customers,

We view with concern policy statements emanating from various health authorities around the world regarding national testing strategies and whether these are to be applied to the vaccinated population. It has been suggested by both the Centers for Disease Control and Prevention (CDC) in the USA and the Robert Koch Institute (RKI) in Germany that vaccinated persons might be exempted from testing arrangements. We are very much opposed to any such policy because of the consequences it would have for the behavior of those who are vaccinated and for our Premium clients.

Essentially, there is no alternative to mass vaccination – it is our only route out of the pandemic. However, not as the sole instrument in our repertoire, as we have been consistently pointing

out for quite some time now. In contrast to the latest pronouncement from RKI, it has to be emphasized that, no matter which vaccination is used, there can never be 100% protection against infection or against the disease taking a severe course. The virus is able to reproduce in the body of a vaccinated person regardless of his or her level of immune protection, and the big risk is that exceptionally dangerous mutations can form there. In the worst-case scenario, the virus becomes able to circumvent the vaccines we have at our disposal. So that we can observe whether the vaccines are losing their effect, it is vital that we closely monitor those who have been vaccinated and ensure that they continue to be tested.

For the last four weeks or so, we have had a very sophisticated antibody profile monitoring system in place for our Salvagene Premium clients. This enables us to gauge very quickly how and to what extent immune protection has been built up as a result of vaccination and how quickly and to what extent this immune protection may be diminishing. The procedure is highly complex and would ultimately not be manageable for a large population, which means that it makes sense for PCR testing to be maintained on a mass scale and for vaccinated persons to be included – at least by means of rapid antigen tests.

The PCR tests are optimized with the CT (cycle threshold) value, as already practiced in the UK and the USA. The so-called "cycle threshold" is a measure of how infectious the individual submitting to the test really is. This advance in test optimization would have to be introduced worldwide.

A large number of studies have all come to the same conclusion, namely that vaccination does not provide complete protection against infection, let alone symptom-free infection. In a study of apparently healthy hospital employees in England, some still tested positive, even after they had been injected with the market-leading BioNTech vaccine, in a ratio of one to four compared with their

unvaccinated work colleagues. So the figure is significantly less, but 25% is still too high.

In another study involving subscribers to an Israeli health insurance fund, 3,000 cases of infection with cough and fever symptoms were registered among 650,000 vaccinated individuals in the course of a single month. Although the majority of these cases also manifested a lower viral load than the unvaccinated with whom they were compared, it cannot be assumed that they were not contagious.

The very latest phase 3 clinical data from both Moderna and BioNTech clearly show reduced efficacy because the more dangerous mutations are now dominant. The latest efficacy data from Moderna is distinctly lower than the rate published just a few months ago.

We have written directly to the Robert Koch Institute in regard to their assertion that "the most frequently used antigen rapid tests have a relatively high filtering effect, especially in people without symptoms." According to RKI calculations, only one in 10,000 persons who test negative is a "false negative", meaning that they are infected after all. Is the probability of encountering an infected person among the vaccinated actually lower than among individuals who have tested negative? Our answer to this is a clear NO. Assuming that a vaccinated but nonetheless infected person is infectious for only one day and not three days as with a non-vaccinated person, then on any given day, six out of 10,000 vaccinated persons would be positive and infectious. On this basis, the AstraZeneca vaccine offers less assurance of protection for persons sharing the same space than a rapid antigen test performed that same day.

The immediate risk of infection to others is worrying enough as it is, **but the situation could become even more dangerous if the viruses in circulation mutate over time and this goes unnoticed because vaccinated people are left out of the testing program.** In this scenario, the virus can adapt to the immune protection offered by vaccination without being detected and can then spread unchecked, including among the vaccinated.

If we take the sum total of vaccinated people in the USA, there is the potential for several 10,000 such infections with so-called escape mutants every day. This is precisely the situation we have been warning about for some time: whenever a vaccination campaign leaves gaps – and this applies in particular to the current pause in the use of the AstraZeneca vaccine – rendering the partially vaccinated vulnerable to infection, then "vaccine-driven evolution" occurs. This means that viruses capable of evading the immune system are more likely to survive in the internal organs of vaccinated individuals. This evolution is the reason why successful vaccines lose their effectiveness over time. A well-known example is the whooping cough vaccine which has become less and less effective over time because the pathogen that causes the disease – the pertussis bacterium – has learned how to conceal itself from the immune system. However, this is a process that has taken years. The new coronaviruses are faster, multiplying at a much higher rate than the whooping cough pathogen. In addition, they can swap larger building blocks, so that SARS-CoV-2 is able to acquire many new properties at a phenomenal rate.

The first thing we discovered about the Brazilian and South African virus variants was that they are resistant to antibodies. Scientists in the USA have now also discovered antibody resistance in the dominant B.1.1.7. variant, which we are also trying to record in our antibody profile monitoring tool. Another colleague of ours, David Ho at Columbia University, is leading a study on this topic. He sees this resistance not as an isolated case but as a general trend. He has expressed the rather gloomy view that the direction of evolution being taken by the virus is towards undermining the

efficacy of the current vaccines. Sadly, we have to concur with his conclusion.

In order to retain an overview of the variants currently in circulation and to detect possible escape mutations at an early stage, the genome of the virus has to be sequenced in detail. The only country that has so far acquired anywhere near adequate capacity for this is the UK. It is therefore important to carry out monitoring of people who have become infected despite vaccination. We have several such cases among our Premium clientele. Unfortunately, this has not been a priority in any country so far. Ideally, a complete genome study would be performed to ascertain the extent to which escape mutations are occurring. In other words, it is important to observe the genome data of the variants circulating among the vaccinated. The sequencing data of the virus would also have to be set alongside the clinical data of these patients. Only in this way can hitherto unknown risk variants be discovered early enough for the vaccine manufacturers to respond.

Take, for example, India which is experiencing by far the steepest increase in new infections – around 300,000 per day. In parallel, we are observing the march of the B.1.617 variant which is responsible for the similarly steep increase in infections in Brazil. We think it is significant that this variant again has two mutations on the surface protein, something we are already familiar with from other similar strains and which we associate with a reduction in neutralizability by antibodies or T cells. We therefore assume that vaccinated or recovered persons are clearly less protected when infected with this variant. Classification by the various authorities, especially the CDC, is still pending. Consequently, we will be returning to this topic.

Globally, it fits the trend, with the number of reported deaths rising for the fifth consecutive week. It took nine months to reach 1 million deaths, then four months to reach 2 million, and now just

three months to reach 3 million. So globally, the pace is really hotting up.

If the pathogen continues to spread at its current rate, more and more critical mutations will accumulate and humanity may well find itself in breathless pursuit of the virus as it seeks its destiny of "self-perfection". We think that the responsible course of action to be taken by the authorities is to clamp down on transmission as quickly as possible, to dramatically increase vaccine production and to continue including the vaccinated in testing procedures.

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