



24 March 2023

**Re: Attestation of Clinical Study Enrollment for SARS-CoV-2 Antibody Testing for Ms. Sheila Annette Lewis**

Please be aware that Ms. Sheila Annette Lewis (hereinafter referred to as “Clinical Study Participant”) has been formally enrolled in a clinical study, entitled “Identification of SARS-CoV-2 Viral Protein Epitopes for Antibodies from Recovered COVID-19 Patients, Healthy and Vaccinated Individuals”, being conducted by Kinexus Bioinformatics Corporation. Our clinical study has received Independent Review Board (IRB) approval. The first phase of our clinical study was ongoing with IRB approval until May 20, 2022, and we are now continuing a second phase in the study.

The primary objective of our clinical study was to identify the most immunogenic sequences in SARS-CoV-2 viral proteins that have been found to successfully elicit antibody production in people who have recovered from COVID-19. These are likely to be protective antibodies in view of their recovery. A secondary objective of our clinical study is to investigate whether immunity to SARS-CoV-2 is conferred in individuals with prior exposure to other endemic coronaviruses. This is a minimally invasive clinical study in which small volumes of blood will be collected by finger-prick on repeated occasions to evaluate and monitor the presence and persistence of natural immunity. The study involves monitoring the antibodies against SARS-CoV-2 that are present in the participant’s blood to check for their binding to membranes that feature, within spots, custom arrays of chemically synthesized peptides that are patterned after the amino acid sequences in the viral proteins. The presence of a spot indicates that the participant has antibodies that will recognize that specific portion of the target SARS-CoV-2 virus protein and likely offer protection against the virus.

To date, Kinexus has monitored over 4000 COVID-19 patients and healthy, unvaccinated controls with our SARS-CoV-2 antibody tests. Our current CCS test utilizes 41 different markers that cover the spike protein as well as 9 additional SARS-CoV-2 viral proteins. These 41 markers were selected from over 8000 potential SARS-CoV-2 markers that we originally screened using serum samples from over 200 fully recovered COVID-19 patients who were confirmed with PCR-positive genetic tests. Our preliminary results have been formally published in the *Journal of Clinical Investigation (JCI) Insight*, which is the peer-reviewed, flagship journal for the American Society for Clinical Investigation (Majdoubi *et al.* (2021) *JCI Insight*. 6(8): e14631 (<https://doi.org/10.1172/jci.insight.146316>). In the *JCI Insight* study, which included serum samples from 276 participants, the Kinexus SARS-CoV-2 antibody test results were cross-validated with another SARS-CoV-2 antibody test developed and marketed by the U.S. company MesoScale Devices. The Kinexus SARS-CoV-2 antibody test is likely one of the most sensitive and accurate serological antibody tests in the world for monitoring immunity to SARS-CoV-2.

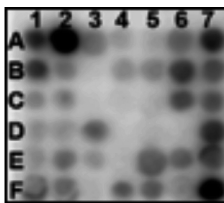
So far, our clinical study results have demonstrated that most of the healthy, unvaccinated participants that we have tested, do, in fact, already have antibodies against SARS-CoV-2. This indicates previous exposure to SARS-CoV-2 or to other endemic coronaviruses that elicit cross-reactivity to and immunity against SARS-CoV-2, thereby mitigating the development of COVID-19 illness. **We have determined that SARS-CoV-2 antibody levels are sustained for at least two years after initial infection for the vast majority of those participants with natural immunity.** Almost all of our vaccinated participants have also been found to have natural immunity, acquired either before or after their vaccination.

The results of the clinical study will enhance our understanding of the prevalence and durability of natural immunity, and whether it is associated with broader coverage against SARS-CoV-2 viral proteins, enhanced immune memory, and a more favourable antibody isotype response (e.g., IgG, IgA, and IgM) compared with current COVID-19 vaccines. As well, the clinical study results may contribute to the development of:

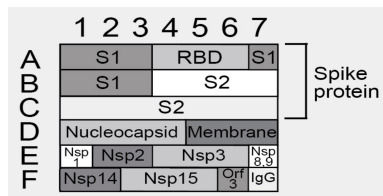
- (i) SARS-CoV-2 vaccines that could offer broader and longer-lasting protection than those currently available;
- (ii) More rapid, sensitive, and accurate serological blood and saliva antibody tests for determining whether an individual has immunity to SARS-CoV-2; and
- (iii) Next-generation antibody treatments for people actively infected with SARS-CoV-2.

The initial results obtained from the testing of the Clinical Study Participant is shown below in the left most image, and clearly supports the presence of SARS-CoV-2 immunoreactivity in her blood sample, as found in many of our other trial participants that have recovered from COVID-19 as confirmed by PCR testing in those cases. A negative control immunoblot image of a person that did not have COVID-19 is shown in the right-most image for comparison. The test of the Participant’s blood sample was performed on a blood sample processed at our facility that was obtained around March 1, 2023. The Participant was likely infected with SARS-CoV-2 originally around September 17, 2021 based on her COVID-19-like symptoms at that time. However, it is evident that she has been further infected since then and has extremely high levels of antibodies against SARS-CoV-2. Weaker signals on our test reflect the duration in time since her SARS-CoV-2 infection, but still clearly demonstrates establishment of natural immune memory in the B cells that produce these antibodies.

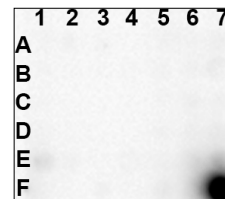
Participant Blot



Map of SARS-CoV-2 proteins tracked



Negative COVID-19 Blot



Please feel free to contact me directly if you have any questions or concerns.

Sincerely,

Dr. Steven Pelech, Ph.D.



**KINEXUS**