

CORONAVIRUS SARS COV-2, SARS COV ANTIGENS, AND RABBIT POLYCLONAL ANTIBODIES

Technology Summary

According to the World Health Organization, the ongoing pandemic of SARS-CoV-2 has resulted in more than 140 million confirmed human cases and approximately 3 million deaths as of April 9th, 2021. Currently there are three FDA approved Covid-19 vaccines; Pfizer-BioNTech, Moderna, and Johnson & Johnson/Janssen. The Pfizer and Moderna vaccines are messenger RNA based vaccines that target the Covid-19 spike proteins. The Johnson Vaccine is a viral vector-based vaccine that targets the Covid-19 spike proteins.

To better understand antibody responses induced by spike protein-based vaccines, investigators at the FDA immunized rabbits with the SARS-CoV-2 spike protein antigens: S-ectodomain (S1+S2), S1 domain, receptor-binding domain (RBD), and the S2 domain (control). Resulting antibodies were characterized using enzyme linked immunosorbent assays (ELISA), receptor binding domain (RBD) competition assays, surface plasmon resonance (SPR) against different spike proteins in native conformation, and neutralization assays. All three antigens (S1+S2 ectodomain, S1 domain, and RBD), but not S2, generated strong neutralizing antibodies against SARS-CoV-2. Additionally, the vaccination-induced antibody repertoire was analyzed by SARS-CoV-2 spike genome fragment phage display libraries (SARS-CoV-2 GFPDL), which identified immunodominant epitopes in the S1, S1-RBD, and S2 domains. These findings may help guide rational vaccine design and facilitate development and evaluation of effective therapeutics and vaccines against COVID-19.

Available Antibodies for Covid-19 Spike Protein Antigens:

- S-ectodomain (S1+S2) (aa 16-1213) cytoplasmic and transmembrane domains (CT-TM)
- \$1 domain (aa 16-685)
- Receptor-binding domain (RBD) (aa 319-541)
- S2 domain (aa 686-1213), control

Potential Commercial Applications

- Covid-19 vaccine and therapeutics
- Vaccine research and development

Competitive Advantages

Analysis of focused Covid-19 antigenic domains

Development Stage: Research Materials

Inventors: Surender Khurana

Publications:

• Ravichandran, A., et. al. Antibody signature induced by SARS-CoV-2 spike protein immunogens in rabbits. Sci. Transl. Med. 10.1126. PMID:32513867

Product Area: antibody, rabbit, coronavirus, SARS, antigen, sera, vaccine development

FDA Reference No: E-2020-016

Licensing Contact:

William Ronnenberg, J.D. – M.I.P., M.S. FDA Technology Transfer Program

Email: FDAInventionlicensing@fda.hhs.gov

Phone: 240-402-2245