MONASH University

Diagnostic Test for Immune Detection SARS-CoV-2 (COVID 19)

The Challenge	Fast, high-throughput, specific and reliable antibody testing is required for confirming SARS-CoV-2 infections (surveillance, contact tracing, asymptomatic carriers) and for monitoring vaccine efficacy, in particular in high-prevalence communities (healthcare workers, airline staff, police, etc). As most people have circulating antibodies against seasonal coronaviruses, any antibody tests need to have low false positive rates due to cross-reactivity.
The Solution	To rapidly develop tests that can be quickly manufactured at scale, we engineered simple agglutination-based blood-typing tests to detect antibodies raised against SARS-CoV-2 in blood. Blood-typing tests are already widely manufactured at scale for use in hospitals in Australia and internationally. This test takes 20 minutes and can be performed manually at ~100-200 samples/hr, or using automated methods (>500 samples/hr).
Key benefits	• Fast (20 minutes); specific to SARS-CoV-2 • High throughput (100-500 samples/hr) • Amenable to manual or automated workflows • Scalable manufacture based on blood-typing components
Development Stage	Proof of principal has been demonstrated on a small cohort of clinical specimens, with samples cross-compared against IgG ELISA and PCR (except for pre-COVID samples; ELISA confirmation only).
Brief Description & Differentiation	Figure 1 demonstrates the process used to engineer SAR-CoV-2 antibody tests from routine blood-typing tests. Both the provisional patent and publication, identified below, are based on the same assay. In a typical blood-typing assay, red cells are incubated with patient samples on a gel card prior to centrifugation to generate a pattern of agglutination results to determine a blood type (Figure 1a). We designed an antibody–peptide bioconjugate, synthesised in a two-step chemical process (Figure 1b), to agglutinate red cells in the presence of SARS-CoV-2 antibodies only. Peptides were designed based on immunodominant epitopes chosen from emerging bioinformatics and experimental studies. In the SARS-CoV-2 serology assay, antibody–peptide bioconjugate-coated red cells are incubated with a patient plasma or serum sample, and the resulting agglutination product is separated from free red cells in a centrifugation step, using a gel-card containing individual wells filled with absorbent beads (Figure 1c). Agglutination products are visible to the naked eye as a red line above the gel media.
Research Team	Simon Corrie, Gil Garnier, Mark Banaszak Holl, Tim Scott - Chemical Engineering Department, Monash University; Erica Wood, Zoe McQuilten, Tony Korman, Maryza Graham - Monash Health.
IP	2020 Australian Provisional Patent application filed.
Key Publication	Diana Alves, Rodrigo Curvello, Edward Henderson, Vidhishri Kesarwani, Julia A. Walker, Samuel C. Leguizamon, Heather McLiesh, Vikram Singh Raghuwanshi, Hajar Samadian, Erica M. Wood, Zoe K. McQuilten, Maryza Graham, Megan Wieringa, Tony M. Korman, Timothy F. Scott, Mark M. Banaszak Holl, Gil Garnier, and Simon R. Corrie, Rapid Gel Card Agglutination Assays for Serological Analysis Following SARS-CoV-2 Infection in Humans, *ACS Sensors*, 2020, 10.1021/acssensors.0c01050