# 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 principle 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 SARS-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
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### IP
2020 Australian Provisional Patent application filed.

### Key Publication