A whole-blood based in vitro assay (Halo Assay) allowing rapid assessment of the haemostasis state of patients. This plate-based assay could be developed into an automated high-throughput diagnostic method to assess thrombolytic defects and thrombolytic therapy approaches.

- Rapid assessment of haemostasis status (less than 30 minutes)
- Whole blood based assay thus providing global assessment
- High-throughput plate based assay using existing diagnostic laboratory instrumentations.

THE CHALLENGE
Pharmacological fibrinolytic therapy is currently the most prevalent treatment for thromboembolic diseases such as acute stroke or myocardial infarction. Unfortunately, these drugs are associated with life-threatening bleeding complications, along with neurotoxic side-effects, and the average benefit to risk ratio provided is extremely low.

Acute thrombosis treatment could be improved by the implementation of new techniques providing rapid assessment of the haemostasis state of patients on thrombolytic therapy.

Current assessment methods include the rheology based techniques thromboelastography (TEG) and rotational thromboelastometry (ROTEM). These are limited by equipment availability, required sample size (300μL of whole blood) and the number of tests which can be run at a time (4 samples maximum). The main alternative method, often referred to as “euglobulin clot lysis time” (ECLT) is exclusively performed with plasma samples, thus eliminating all the circulating blood cells which play a major role in thrombolysis.

THE TECHNOLOGY
Monash researchers have developed an easy to implement, high-throughput, whole-blood based in vitro thrombolytic assay which can potentially overcome the limitations of current methods. The thrombolytic assay allows for identification of hyperfibrinolytic or hypofibrinolytic states associated with surgery and trauma, thrombolytic therapy management in obstetrics, myocardial infarction, ischemic stroke and chronic coronary disease.

The method consists of monitoring the lysis of halo-shaped clots via the change in absorbance due to red blood cells released by degradation. The technique requires a low blood volume (25μL), while keeping the measurements relevant to thrombosis physiopathology, as it does not exclude significant blood components (compared to ECLT assay which is restricted to the euglobulin fraction).

We have designed and tested assay plates that would allow automation of the assay in high throughput fashion, employing diagnostic laboratory liquid handling and absorbance systems.

THE OPPORTUNITY
We seek a partner to commercialise and further develop the assay as a clinical diagnostic method.

Intellectual property: Provisional Patent application (AU2017901719) on assay microplate and assay method for thrombolysis testing and measurement.