

Optically stimulated piezofilm detection for point-of-care immunoassay

A novel, sensitive, non separation assay designed for point-of-care applications

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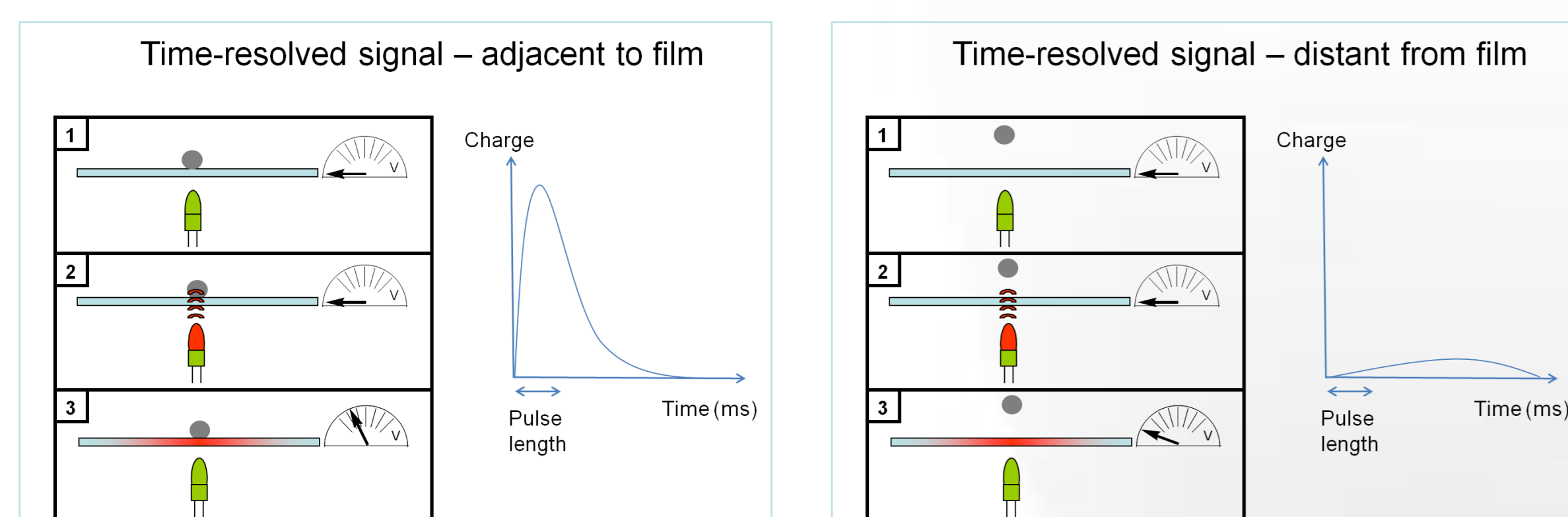


Introduction – the Company

Vivacta is a venture capital funded start-up company based at Kent Science Park in the UK. The company now has 30 employees and has raised more than £9 million through 2 funding rounds. Spark Ventures, AGF, HBM and Viking have participated in this funding.

The Technology

Polyvinylidene fluoride (PVDF) is an inexpensive piezo- and pyro-electric polymer which generates an electric charge when subjected to a thermal or mechanical stress. Such stress can be generated by micro-heating of particles upon illumination by pulses of light. This localised heating stresses the film, creating a charge which can be amplified using simple electronics. Time resolution of the signal allows discrimination between particles close to the surface of the piezofilm and particles distant from the surface.



This ability to distinguish spatially between particles in a sample makes this detection method ideal for immunoassay applications because there is no need to separate bound and free label during the measurement process. Coupled with the low cost of the components, the technology is ideally suited for point-of-care applications.

Components

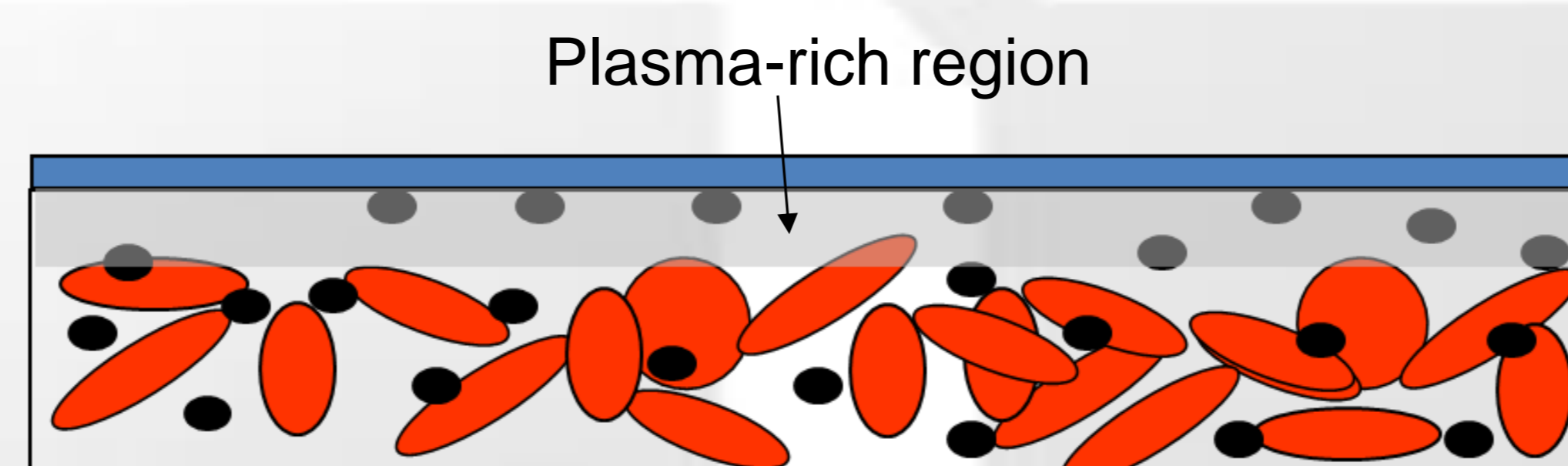
Carbon particles (approx 100 nm) are ideal for signal generation, since they are strong absorbers at all visible wavelengths. Antibody is readily coated onto the surface of the piezofilm using a proprietary method.

The system works under diffusion control – sample and dried reagents are mixed in the cartridge, then transferred to the piezofilm. The cartridge then monitors the reaction kinetics as the carbon picks up analyte in solution, then diffuses and binds to the surface.

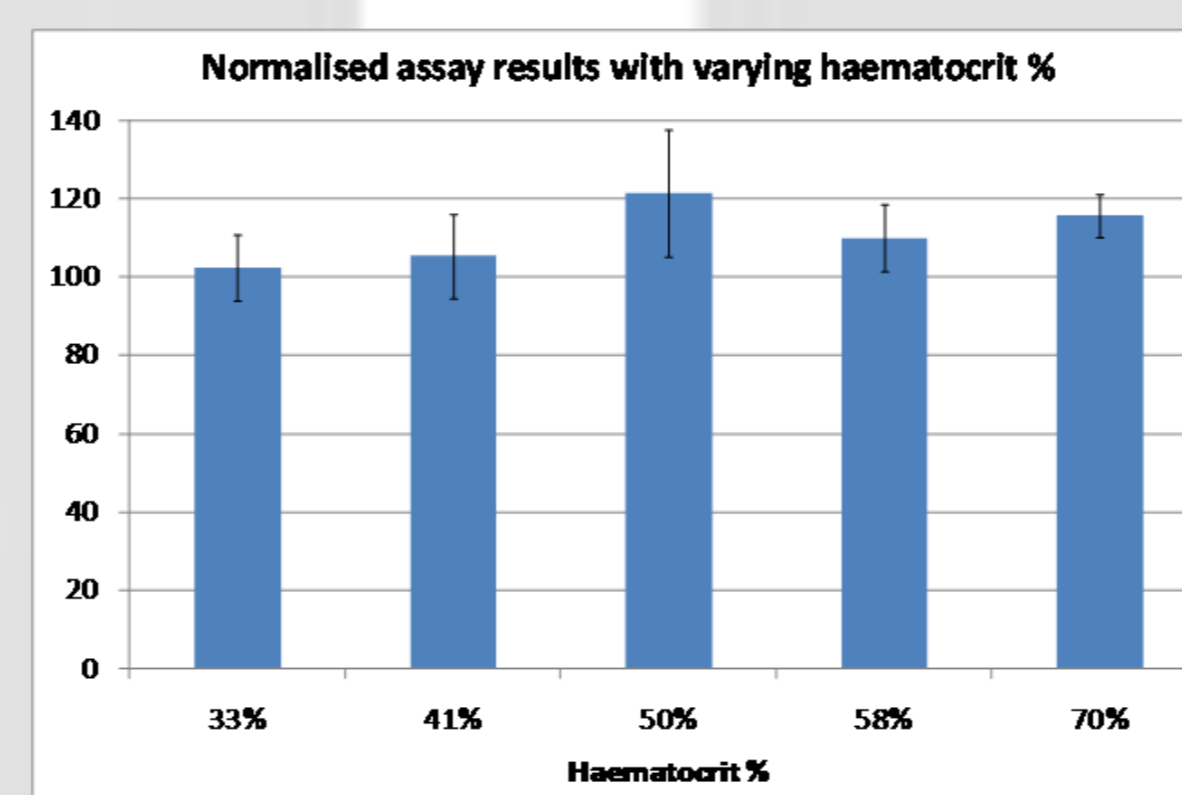
There are no separation steps or wash steps – the signal is generated *in situ*.

Whole blood measurements

For optimum signal in whole blood, the piezofilm is oriented above the sample. Sedimentation of red cells creates a natural plasma-rich layer at the interface of film and sample.



Since the kinetics are governed by the plasma concentration of analyte there is no need to make a correction for hematocrit and the output is the actual plasma concentration of analyte, as illustrated below.



Disposable cartridge

The piezofilm is incorporated into an injection-moulded disposable using simple lamination processes. The cartridge also incorporates a blood collection capillary and all additional reagents are dried-down on-board. Three chambers allow a negative and positive control measurement to be made simultaneously.



Instrument development

Experimental work to date has been carried out on “breadboard” type instruments. Development of a commercial reader is currently underway, with the first prototype due for delivery in April 2009 and a further 50 instruments due to be delivered in August 2009, with clinical trials anticipated in Q4 2009.

Overall performance

The first commercial product is a point-of-care TSH test. TSH has been chosen as the first analyte for a number of reasons; the demanding requirements in terms of dynamic range and detection limit, coupled with an unmet need for a TSH test at the point-of care. The current detection limit of the system is 0.075 mIU / mL (~20 pg / mL). A dose response curve in whole blood is shown

