

Integrated POC lateral flow device for Cardiac testing

At A Glance

Customer

Biotech company

Product

Point-of-Care device for molecular diagnostics applications

Services/ Market

Biotech, Healthcare

Challenge

The principal challenge was in integrating the sample collection portion of the device with the lateral flow device. The device required onboard storage and delivery of a buffer solution. In addition, a defined volume of blood had to be collected and diluted, before plasma separation using a filter stack of varying pore sizes. Once filtered, the plasma was delivered to a lateral flow device, all in a single motion by the end user. The geometry of the plastic had to accommodate a lateral flow strip such that flow was optimized while preventing the strip from moving within the plastic housing.

Summary

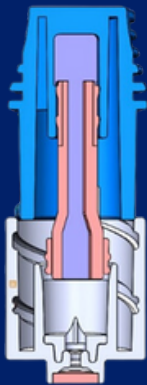
A biotech startup customer specializing in point-of-care molecular diagnostics, approached Gener8 requesting the development of a rapid, integrated lateral flow IVD platform for the detection of cardiac markers.

Methods Employed

Gener8 designed a luer lock mechanism whereby the sample collection device was attached to the lateral flow device. Within the sample collection device, a plunger could be screwed downward onto a spike which pierced a foil seal, causing the blood sample to be released. The blood then wicked through the filter layers to separate red blood cells from plasma.

A syringe pump was used to load the storage buffer into the sample collection device before being sealed. The buffer had a two-year shelf life. Gener8 performed a study to optimize plasma separation. An off-the-shelf filter housing was used to minimize cost and time. Various stack configurations (material, pore size, asymmetry, etc.) were evaluated and optimized for the desired performance characteristics, as well as material to reduce red blood cell (RBC) hemolysis.

The plunger of the collection device was designed using polypropylene with an elastomer overmold. The lateral flow pieces, fabricated using polycarbonate, were press-fitted together.



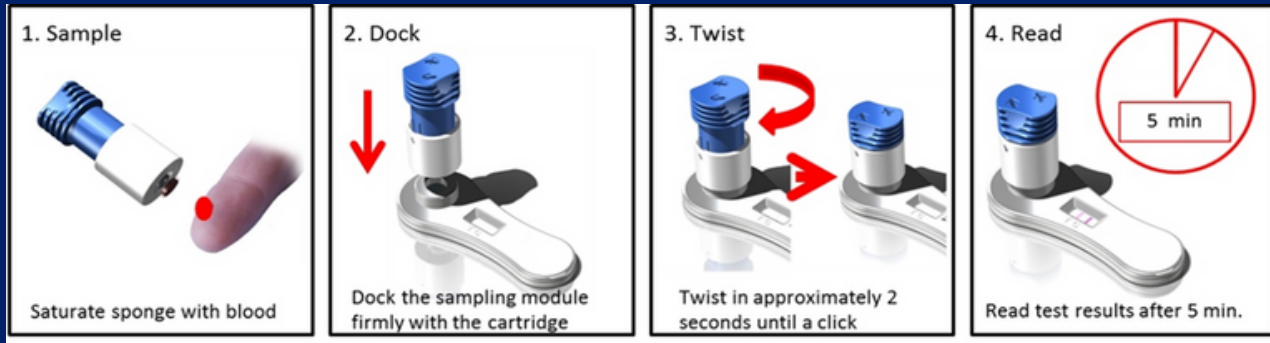
Side view of CAD for the collection device.



Side view of CAD for integrated lateral flow IVD device showing both collection and lateral flow components.

Solution

Gener8 met the customer's requirements in designing and developing a simple, easy to use, CLIA-waived method for rapid isolation of plasma from blood through the incorporation of a custom filter stack. The selected filter stack contained membranes of decreasing pore sizes and various combinations of filter materials that reduced RBC hemolysis.



Expertise Employed

- Microfluidics design and testing
- Material science (membrane/filter selection)
- Computational fluid dynamics
- Low volume manufacturing for clinical trial studies
- Project Management

