

# Semi-Automated Microfluidic Device for POC Molecular Diagnostics

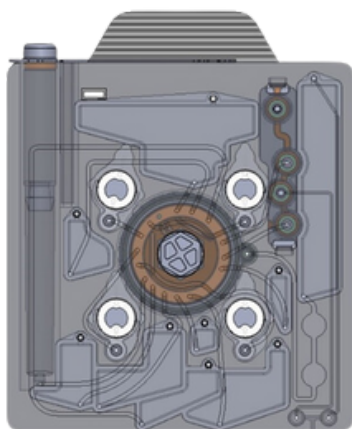
## Summary

A biotech startup customer specializing in point-of-care molecular diagnostics, approached Gener8 requesting the development of a semi-automated PCR system. The customer requested Gener8 to use their patented infra-red LED technology to perform PCR.

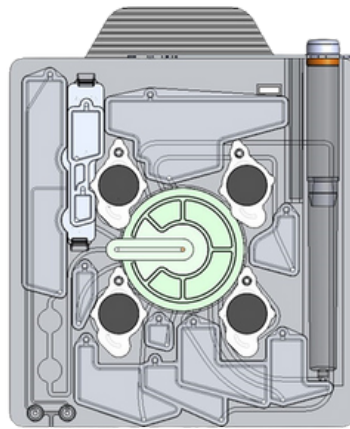
## Methods Employed

Gener8 designed a consumable consisting of double-sided rotary valve that opened and closed via a mechanical actuator. The cavities in the rotary valve were used to meter the sample aliquots delivered to each well. Mixing of the beads: beads were resuspended by repeatedly moving the sample solution back and forth between two chambers and usual optimal microfluidic channel geometry. The lyophilized beads and magnetic beads were loaded during manufacturing. The cartridge design included mixing and target capture areas. PCR cycling was performed by pulsing the infra-red light which facilitated rapid heat cycles for the reaction.

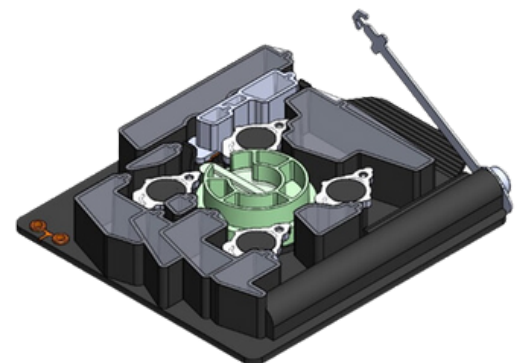
The cartridge was designed out of multiple materials enabling processes such as laser welding and detection through optically clear windows.



Bottom view of CAD for PCR cartridge.



Top view of CAD for PCR cartridge.



Isometric view of CAD for PCR cartridge.

## At A Glance

### Customer

Biotech company

### Product

Point-of-Care Device for POC Molecular Diagnostics

### Services/ Market

Biotech, Healthcare

### Challenges

The principal challenge was to condense a 28-step assay into a small point-of-care cartridge. The challenge involved designing an instrument-driven consumable containing multiple reagents including lyophilized beads, magnetic beads, wash buffers, lysis buffer and binding buffer. The instrument had to be capable of running four PCR reactions simultaneously. Another challenge was to fully resuspend the magnetic beads to maximize the lysed nucleic acid yield from the sample swab (saliva/nasopharyngeal). The beads had to then be pulled down very effectively so as not to be inhibitory to the PCR cycling. Due to the detection requirements, the material on the bottom of the cartridge had to be optically clear.



Bottom view of the commercially available device.



Top view of the commercially available device.

## Solution

Gener8 met the customer's requirements in designing and developing a simple, easy to use, cartridge for PCR applications. The 28-step assay was self-contained with the cartridge. Lysed samples attached to the magnetic beads flowed into a mixing chamber to the capture chamber where they are held with a magnet and washed. The four PCR chambers contained metallized surface to facilitate heat transfer via the infra-red light. An optical window on the opposite side allowed for fluorescence detection.

## Expertise Employed

- Microfluidics design and testing
- Computational fluid dynamics
- Thermal controls
- Laser welding
- Project Management