Wainamics

It makes sense for you to have a fluidic cartridge for your POC medical diagnostics. So, do you have 'cartridge sense'?

It's a tortuous path from POC diagnostics invention to product launch. You need more than an assay and microfluidic automation. The intersection of regulatory compliance, materials, engineering, surface chemistry, assay integration and manufacturability complicates your development plans. Without 'cartridge sense', prototype specification oversights can stagnate your progress and increase your product development time.

Reduce development time

Reduce your development time by using Wainamics microfluidics cartridge services. Wainamics applies broad expertise in biological samples and assays, materials science, engineering, surface chemistry, and manufacturability to deliver the design need with the optimum materials for your assay. Product development services include post-market surveillance, data collection, and documentation with FDA and CE approval in mind.

Cartridge sense with Wainamics

- Cartridge design
- Material selection
- Surface treatment
- Rapid and affordable prototyping
- Injection molding
- Reagent storage
- Packaging
- Preclinical and bench top study design & documentation
- GLP final reporting to FDA
- Liaison to regulatory agencies as well as writing submissions

Assay integration and validation

Wainamics co-develops a validation protocol that helps you test your design's interaction with your assay specifications. Wainamics delivers more than a cartridge. We give you a cartridge with materials optimized for your assay.

Get cartridge sense. Contact Wainamics for a free 30 minute consultation.

www.wainamics.com

Turbocharge your cartridge development

3135 Osgood Court| Fremont, CA 94539 | (925)640-2031 | info@wainamics.com

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Case Study: Point of Care Diagnostic for HIV

The situation

A client created a new product measuring the CD4 cell count in whole blood for HIV treatment in the developing world. The product required a disposable fluidic cartridge integrated with the optical imaging technology for the product.

The challenge

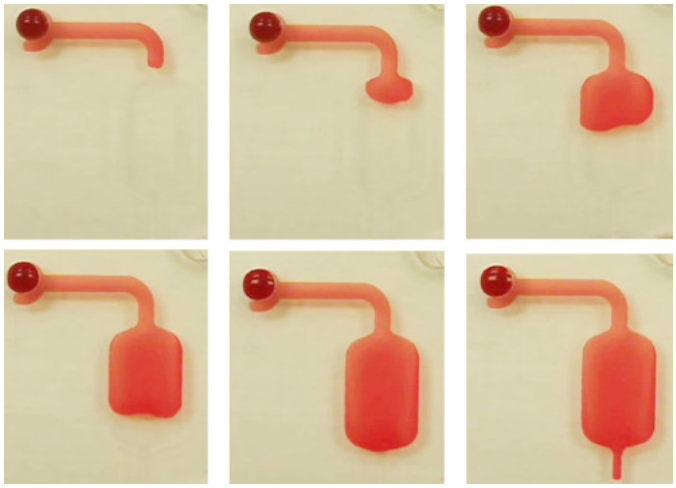
The cartridge required the passive flow of whole blood into a reaction chamber, uniform mixing with fluorescence tag reagents, continuing to a detection chamber with an optical window. Sample volume precision was within 10%. The target cost per cartridge was <$1.00 USD.

The solution

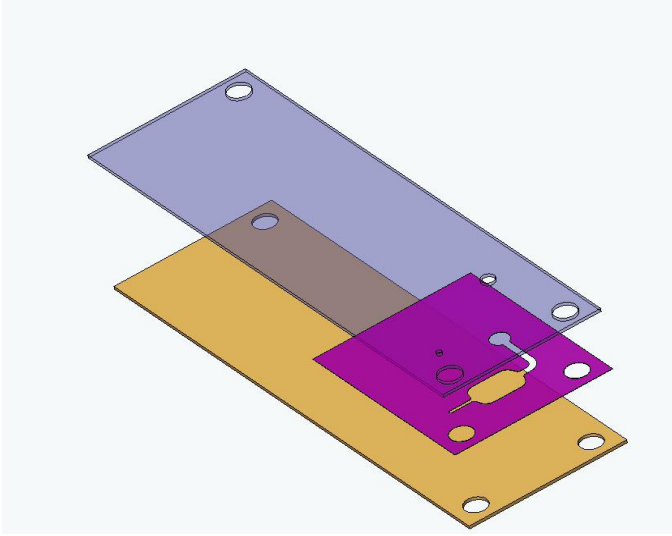
Because we used laser cutting and plastic-PSA lamination, we were able to deliver prototypes less than two weeks into the project. The prototypes included surface modifications added to create uniform reagent mixing in the cartridge. After testing more than ten prototype configurations, a design was selected. One thousand cartridges were then fabricated and used in assay validation and verification tests.

The result

Rapid prototyping enabled simultaneous assay testing and cartridge development. Scalable process development ultimately resulted in one thousand cartridges produced at a cost below $1.00 USD per cartridge for use in clinical trials. The product was successfully launched in 2014.



Whole blood passively flowing into low cost laminated fluidic cartridge for CD4 cell counting.



Consumable cartridge built for passive filling with whole blood.

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