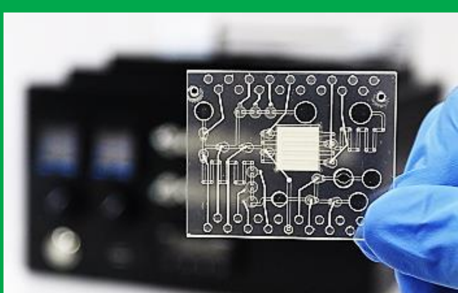
Microfluidic Engineering

Our Design and Development Strategy

- Product design for injection molding and cost-effective assembly
- Engineered laminate 'smart capping-layer' to expand range of functions (valves, vents, pumps, etc.)
- Sensor integration: optical or e-chemical
- Reagents - blister packs, dried, spotted
- Materials selection and verification

Instrumented Control of Devices

- Modular & Custom Instrumentation
- Suitable for handheld applications
- Pneumatic, Flow, and Thermal Control
- Semi-automated control for accelerated assay optimization
- Minimize user error, move more quickly to optimized assay performance.



Working with ALine:

- Discussion of application & requirements
- Sign Confidentiality agreement
- Detailed review of desired product application and development strategies
- Engineering Proposal with detailed work plan addressing high risk elements first
- Modular Approach to down select best performing fluidic components
- Integration to provide complete workflow
- Delivery of devices for assay development
- QC protocol & videography to support semi-automated testing
- Assay optimization with iterative cartridge and reagent optimization
- Scale for clinical trial
- Prepare for early commercial launch.

Microfluidic Design, Engineering and Production

Lab-on-Chip products require execution of the target assay as early in the development as possible. Whether your product has ***passive or active fluid control***, the sooner the entire workflow is integrated and managed in a repeatable fashion, the better the final product design.

Objective: ***measurements with the target assay within the first six to 12 weeks of development***. From experience, once the microfluidic cartridge is operated in a repeatable, semi-automated fashion, further design modifications are required.

Addressing workflow and interface issues early accelerates assay development and optimization. Rapid transition to semi-automation or controlled testing shortens the time to achieve an optimized assay.

Engineering Program Tailored to the Level of Support Needed

Level I Engineering program – Support for translating an existing design into a production-friendly product. (1 – 3 weeks)

- Quote for production of small lots
- Process verification for high volume production compatibility
- Deliver quote for high volume runs

Level II Engineering Program – Develop limited scope program to address one key risk area in the cartridge development. (1 - 3 months)

- Small lots of devices produced with process suitable for scale-up
- In-house verification and optimization of functional performance
- After customer evaluation, provide quote for larger batch runs

Level III Engineering Program – Structured work plan with deliverables & timeline (9 - 18 months)

- Program organized to identify and solve key risks & challenges
- Modular development using pre-engineered fluid components.
- Functional modules integrated & optimized in a stepwise process
- Performance benchmarking & optimization with customer's assay data
- Development of critical QC protocols
- Detailed reporting of functional test results, including videography,
- Protocols for semi-automated device control with development instrument to accelerate the assay optimization process.

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Microfluidic Fabrication

Product Development Process

Proof of Concept:
Batches of 10 to 30 parts
2- 5 Design iterations over 1 – 3 months
Cost: per batch $1500-5000 USD

Development Beta 1
Batches of 100 – 200
Root Cause Failure Analysis
Design, material refinement
Cost per piece: $10-200 USD

Development Beta 2
Batches of 100 – 200
Evaluate interface & assay reproducibility issues, lock down materials, optimize design
Cost per piece: $10-200 USD

Prepare for Clinical Trials
Batches of 3000- 6000
Cost per piece $2-25 USD

Product Launch
Blanket purchase for pilot production,
Build supply chain for high volume manufacture.
Cost per piece: $1-15 USD

Facilities

Class 10,000 Clean Room
Multi-layer Lamination
Laser Machining, 3D Printing
Pick & Place/ UV Bonding Automation
Injection/Compression Molding
Surface Modifications & Metrology
Application & Testing Lab
Ultrapure water system

Shorten the Development Process

Methods to iterate quickly through the Design-Build-Test Cycle

We combine techniques including:

- Engineered Laminates
- Machining
- Silicone Molding
- 3D Printing
- Injection Molding

ALine's Engineered Laminate Platform is a computer automated method for creating complex fluid circuits that integrate on-board valves, vents and pumps by machining features in different layers or sheets. The layers are then stacked, aligned and bonded in a batch fabrication process.

Integrated Functional Solutions

- Incorporate electrodes, membranes, on-board valves & pumps
- Integrate optical and electro-active sensors; PCBs, silicon and glass
- Integrate injection molded components and blister packs
- Reagent deposition
- Pop-on fluidic components that interface to a fluidic 'motherboard'

ISO9001:2008 Certified, and ISO13485 Compliant.
Assembly in a Class 7 Cleanroom
QA Processes: Metrology and Pressure Decay Testing.

Material	Thickness
PMMA	.002" to .177"; 50 microns to 4.5 mm
ACETAL	.005" to .125"; 125 microns to 3 mm
PET	.0005" to .010"; 12.5 to 250 microns
POLYCARBONATE	.005" and .010";125 and 250 microns
POLYSTYRENE	.0002" to .005"; 6 to 125 microns
POLYPROPYLENE	.002" to .040"; 50 to 1 mm
COP	.002" and .007"; 50 and 175 microns
SILICONE	.005" to .060"; 125 micron to 1.5 mm
POLYIMIDE	.001" to .005"; 25 to 125 microns
FLUOROPOLYMERS: FEP, PTFE, PVDF	.001" to .010"; 25 to 250 microns

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