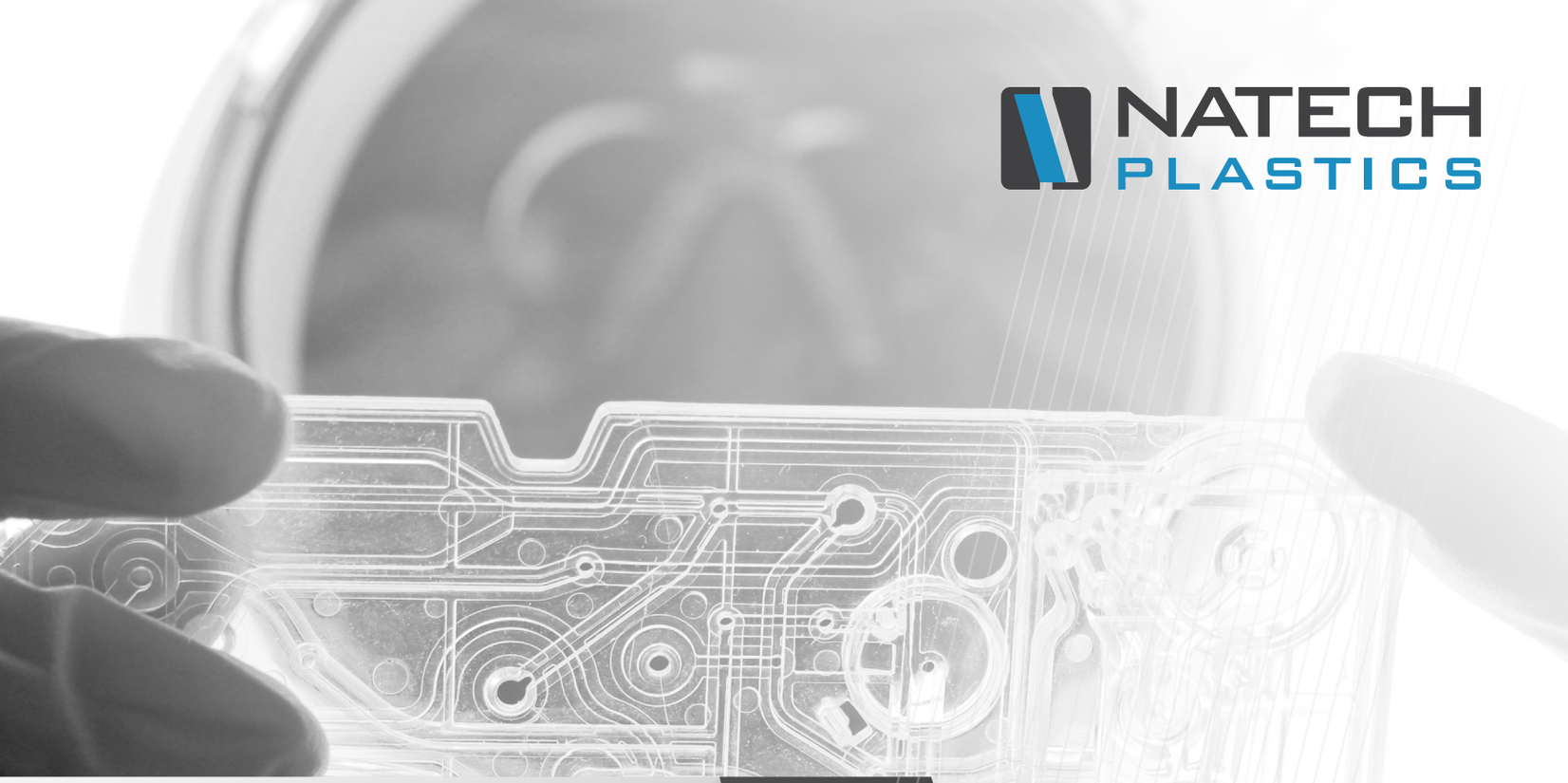
NATECH PLASTICS



DIAGNOSTICS CONTRACT DEVELOPMENT & MANUFACTURING

SOLUTIONS

- Lateral Flow
- Fluidics & Microfluidics
- Design for Manufacturing
- Injection Molding
- Filling & Sealing
- Startup Solutions

NATECH PLASTICS
631-580-3506
WWW.NATECHPLASTICS.COM

LET'S CREATE LIFE-SAVING

New and disruptive life-saving opportunities are rapidly occurring in the diagnostics space. These products need to launch and scale at an accelerated rate.

For over two decades, Natech has brought ideas to life as the contract development and manufacturing organization for the IVD industry.

Our expertise in manufacturing for lateral flow, molecular diagnostics, and microfluidics will help move your ideas from concept to commercialization.

Together, let's bring your life-saving ideas to life and make sure great products get made.

NATECH PLASTICS

HOW NATECH SUPPORTS YOU:

- Product design and design for manufacturing for IVD & life sciences
- ISO 9001 & ISO 13485 Quality Systems
- FDA-Registered facility
- State-of-the-art inspection equipment
- Injection molding and assembly for R&D and high-volume production
- Filling & sealing with on-board reagents and solutions
- Planning and scaling for future growth

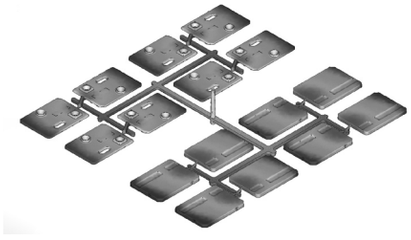
FROM CONCEPT TO COMMERCIAL

We move your application from initial concept through final product.

DESIGN & DEVELOPMENT

Optimize Your Design

Conceptual Design
Design for Manufacturing
Design for Assembly
MoldFlow Simulation



PROTOTYPING

Prove Out Your Concept

R&D Moldmaking
Material Testing
Sampling & FAI
Low-Volume Manufacturing

INJECTION MOLDING

Precision Mold Your Product

IQ/OQ/PQ
Single & Multi-Cavity Molds
Cleanroom Manufacturing
Scientific Processing

For a more efficient, cost-effective and reliable product launch.

DEVICE ASSEMBLY

Manual & Automated Assembly

Ultrasonic Welding
Heat Staking
Mechanical Joining
Automated Assembly

Unit Dose Consumables

Product Filling
On-board Reagents
Foil Sealing
Device Capping

FILLING & SEALING

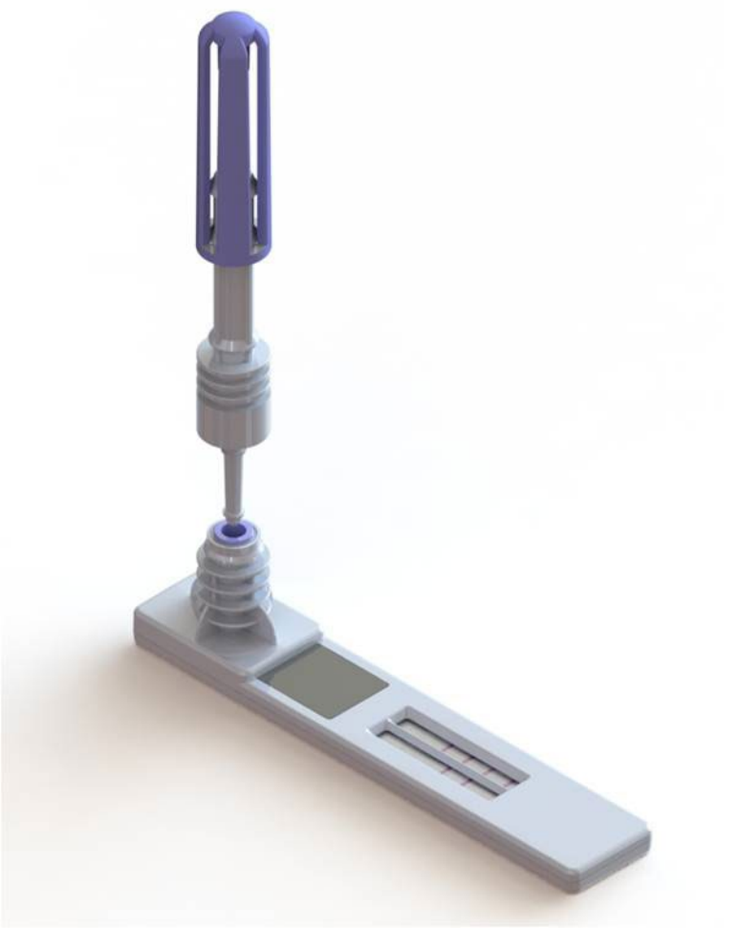
PACKAGING & LABELING

Custom Packaging and Labeling

Blister Packaging
Kitting
Pouching
Pad Printing
Labeling

LATERAL FLOW

Lateral flow cassettes, sample collection devices, and instruments.



SMOOTH TRANSITION FROM R&D TO PRODUCTION

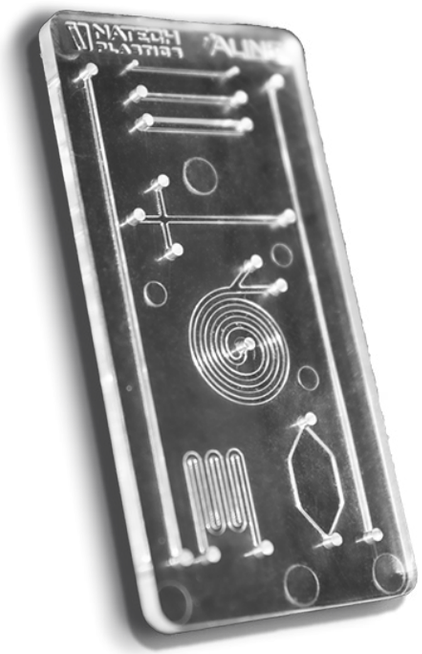
Moving from R&D to production for lateral flow products should be a smooth and scalable transition. Natech's engineers design and implement processes to allow you to quickly ramp up your production.

Capabilities Include:

- Design for Manufacturing and Assembly
- Engineered design of pins and bosses for a reliable fit
- Design of pressure points for accurate interference with lateral flow strip
- Lateral flow product injection molding
- Lateral flow cassette assembly
- Lateral flow device assembly
- Packaging and labeling

FLUIDICS & MICROFLUIDICS

Achieve tight tolerances, precise features and smooth finishes with your fluidic and microfluidic chips.



Ultra-small features and tight tolerances are necessary in fluidic and microfluidic applications. Your plastic application relies on channels and microchannels to move fluid, and Natech's engineers have the expertise to design, manufacture and assemble your fluidic chips.

QUALITY IN FLUIDICS & MICROFLUIDICS

Conventional tools are not appropriate for measuring channels in your fluidic devices. Natech invests in state-of-the-art equipment to inspect channels as low as 25µm in width and hold tolerances of +/- 4µm.

Microfluidic Capabilities:

Small, Precise Channels and Features
Natech manufactures microfluidic chips with channels as small as 25µm x 25µm. Common channels range from 250µm to 500µm.

Tight Tolerances and Complex Geometry
Our engineers can achieve tight tolerances in the injection molding process for +/- 4µm tolerances.

Smooth Surface Finishes
The team at Natech can achieve an A-1 surface finish with our high-performance steel molds.

Mastery of Materials in Microfluidics
We have experience injection molding microfluidic chips with materials such as COC, COP, PMMA and PC.

QUALITY & MANUFACTURING

Have confidence in part quality from design through final product.

Natech's QA and QC teams develop and execute quality plans for each part manufactured at Natech Plastics. Because the quality of your IVD products is critical to proper functionality and testing, our teams have designed processes to give you confidence in your part beginning on day one.

QUALITY SYSTEMS

Ensuring that each part and process meets the strict standards and demands of IVD device manufacturing:

- ISO 9001:2015
- ISO 13485:2016
- FDA-Registered Facility
- ISO Class 8 Cleanroom

CAPABILITIES

Reducing client risks and increasing part quality through tactical and strategic processes:

- Risk Assessment (FMEA)
- In-house Metrology
- Design History Files
- Tolerance Stacking

PROCESS VALIDATION

Having a consistent and stable process for manufacturing IVD products:

- IQ/OQ/PQ
- Scientific Molding
- Statistical Process Control (SPC)
- Design of Experiments

We are your partner in manufacturing from R&D through high-volume production

INJECTION MOLDING

- 20+ Years of Experience in IVD Molding
- >25,000 sq ft of Manufacturing Space
- 40-400 Ton Injection Molding Machines
- Cleanroom Manufacturing
- Low & High Volume Production
- Manufacturing Cells
- Material Processing Experience with Complex Resins, such as COC, COP, & PMMA

AUTOMATION

- Machines Equipped with 3-axis Robots and Conveyor Systems
- Lights-Out Manufacturing
- Collaborative Robots (Co-Bots)
- Automated and Semi-Automated Manufacturing Work Cells
- Custom Automation Solutions for IVD Products
- Scalable Solutions Moving from R&D to High-Volume Production

FILLING & SEALING

Filling and sealing with on-board reagents, antiseptics and buffer solutions with Natech Plastics.

After injection molding, many IVD products require filling and sealing with various liquids and reagents.

Natech's team of engineers develop customized solutions for low and high volume production. This includes custom stations, automated processes, custom packaging and final assembly.

FILLING & SEALING CAPABILITIES:

- Custom filling and sealing stations
- Automated filling processes
- Foil sealing and capping
- Filling of on-board reagents and solutions
- Custom trays and packaging
- Blister packaging

CUSTOM SOLUTIONS

EXTRACTION TUBE

Metered-dose custom Extraction Tube

Natech's IVD clients have struggled to find a reliable supplier for extraction tubes. To overcome this challenge, Natech's engineering and manufacturing teams developed a custom extraction tube.

This extraction tube is able to be manufactured, filled, sealed, and packaged at Natech Plastics. You can customize this product to fit your diagnostics testing needs.

FEATURES & BENEFITS

- Raw Material Traceability
- Quality Lot Consistency
- Foil Seal and Capping Options
- Reagent and Solution Filling Options
- Permeability-Tested
- Tube Clarity
- Product Ductility
- Custom Trays & Packaging

WE HELP STARTUPS AND INNOVATORS DEVELOP AND SCALE THEIR PRODUCTS

Exciting developments in the life sciences and IVD markets mean more opportunity for industry startups, innovators and disruptors. Our mission at Natech Plastics is to make sure great products get made, and we have developed solutions to help innovators launch and scale their game-changing products.

SOLUTIONS FOR STARTUPS & INNOVATORS

- Product design and development
- Design for Manufacturing
- Scaling and Next-Gen Development Plans
- Streamlined Automation and Manufacturing
- Cost of Goods Sold (COGS) Reduction Planning
- Manufacturing Redundancy Planning

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