

# atomo diagnostics

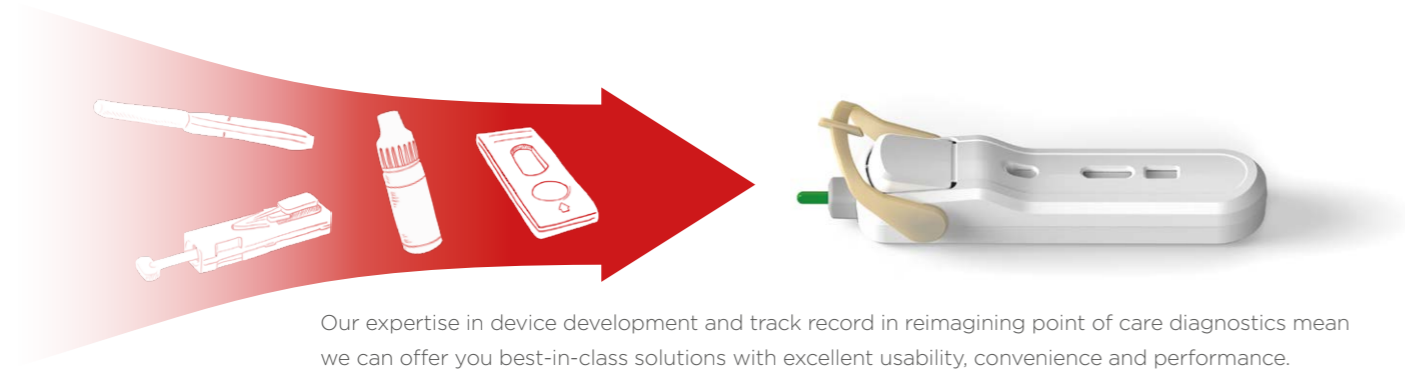
SIMPLY BETTER DIAGNOSTICS

## Custom Device Manufacturing Services

Enhancing rapid  
diagnostics through  
innovation



# Reimagining Your Rapid Diagnostic Test



Our expertise in device development and track record in reimagining point of care diagnostics mean we can offer you best-in-class solutions with excellent usability, convenience and performance.

## AtomoRapid™ Integrated Device Solutions



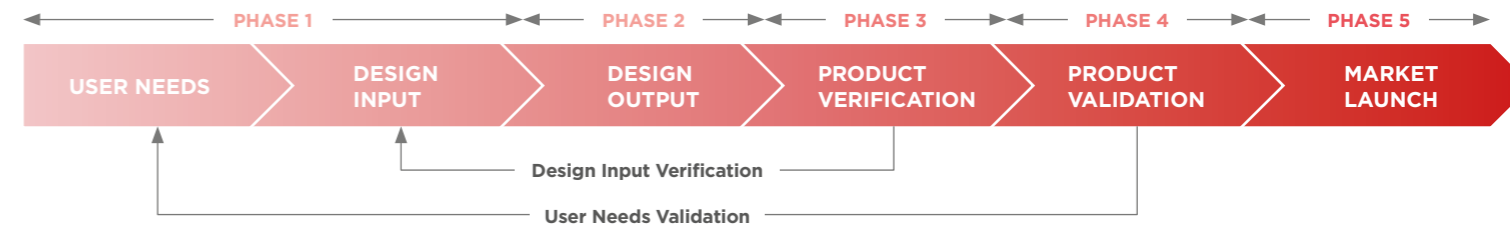
Our unique and award-winning AtomoRapid lateral flow RDT platforms are fully customisable to suit your requirements and can be adapted to match the specifics of your test strip.

Atomo device technologies put the end user first, simplifying test procedures, mitigating common user errors and enhancing test performance.

DESIGN FEATURES	BENEFIT
All-in-one test device	Greater convenience and usability
Contact activated, auto-retracting safety lancet	Safeguards against needlestick injuries and cross-contamination
Controlled blood collection and delivery	Simplifies test procedure Improves blood volume accuracy Delivers blood to the correct location on the test strip
Delivery of integrated buffer solution at the push of a button	Guarantees correct buffer volume Removes the need for separate buffer bottle Fewer user errors
Interlocked, sequenced user steps	Ensures compliance with test procedures Fewer user errors
Digital reader and display	Eliminates result interpretation errors Improves usability eHealth capabilities
Two test strips in one device	Greater convenience and usability Two test results from a single finger prick Cost effective solution

# Custom Device Development Pathway

Atomo's robust product development process is compliant to ISO 13485 and FDA 21 CFR 820 and provides a rapid and effective route from design to commercialisation.



### Phase 1 and 2: Design, Prototyping and Pilot Production

- Analysis of user requirements
- Concept feasibility studies
- Development of functional prototypes
- Human factors research & user testing
- Management of intellectual property

### Phase 3 and 4: Verification and Validation

- Clinical validation
- Company-wide Quality Assurance
- FMEA manufacturing process analysis
- Design History Files (DHF)
- Device History Records (DHR)
- Device Master Records (DMR)
- Support with regulatory submissions

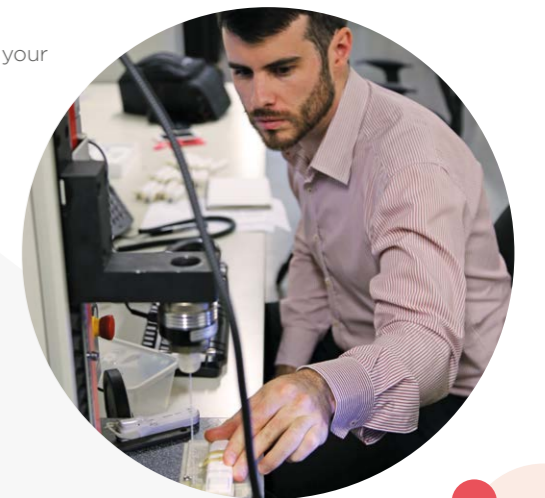
### Phase 5: Commercial Launch and Rollout

- Full manufacturing process validation
- High quality manufacturing and assembly facilities
- Brand, packaging and marketing assistance
- Post launch support

## Benefit From Our Expertise

Atomo will partner with you to create user-centered solutions that will enhance your RDT offering, whether you are seeking to introduce new test applications or to upgrade and reinvigorate an existing product. We offer custom modifications of existing AtomoRapid platforms or bespoke product developments to meet specific requirements.

- ✓ Design and Innovation
- ✓ Regulatory Affairs
- ✓ Manufacturing
- ✓ Final Assembly



## Case Study

### Helping in the fight against Ebola






BBI Solutions, a leading global expert in lateral flow assay development, chose the AtomoRapid 'Galileo' platform for use with its Ebola RDT. It was selected to maximise test performance, usability and safety for deployment in some of the world's most challenging healthcare environments.

**"AtomoRapid represents a new standard in usability for lateral flow testing and perfectly complements the product offerings and focus on innovative solutions that BBI is known for."** Leigh Thomas, BBI Solutions, Chief Commercial Officer, BBI Media Release, November 4, 2014



## The AtomoRapid™ Range of RDT Platforms

The AtomoRapid RDT platform portfolio includes devices with assorted functionality to meet in-market needs and are suitable for use with most lateral flow test strips. Our commitment to usability and simplicity in design means the devices can be deployed for both professional use and self test applications.

ATOMO OEM PLATFORMS		FEATURES					
		Integrated Lancet	Integrated Blood Collection	Integrated Buffer Solution	Digital - LED Display	Digital - LCD Display	Dual test strip
Galileo		●	●				
Pascal		●	●	●			
Losev		●	●	●	●		
Newton		●	●	●		●	
Fleming		●	●				●

● In Development

## About Atomo Diagnostics

Atomo is a specialist medical device design and original equipment manufacturing (OEM) company with unique proprietary technologies that improve rapid diagnostic testing by emphasising ease-of-use, accuracy and performance. Atomo's patent and platform device portfolios provide an efficient and low-risk pathway from product development to commercialisation of your test.

## Quality Assurance & Regulatory

Atomo's operations are ISO 9001 and ISO 13485 certified for the design, development and manufacture of in vitro diagnostic medical devices. All OEM projects include support in the development of technical and risk management files.



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**atomo** diagnostics

## Design & Innovation Awards

Atomo's commitment to innovation in point of care diagnostics has been recognised with multiple international awards.

