



Complete Lateral Flow Test Outsourcing Solutions

Effective development. Reliable Manufacture.

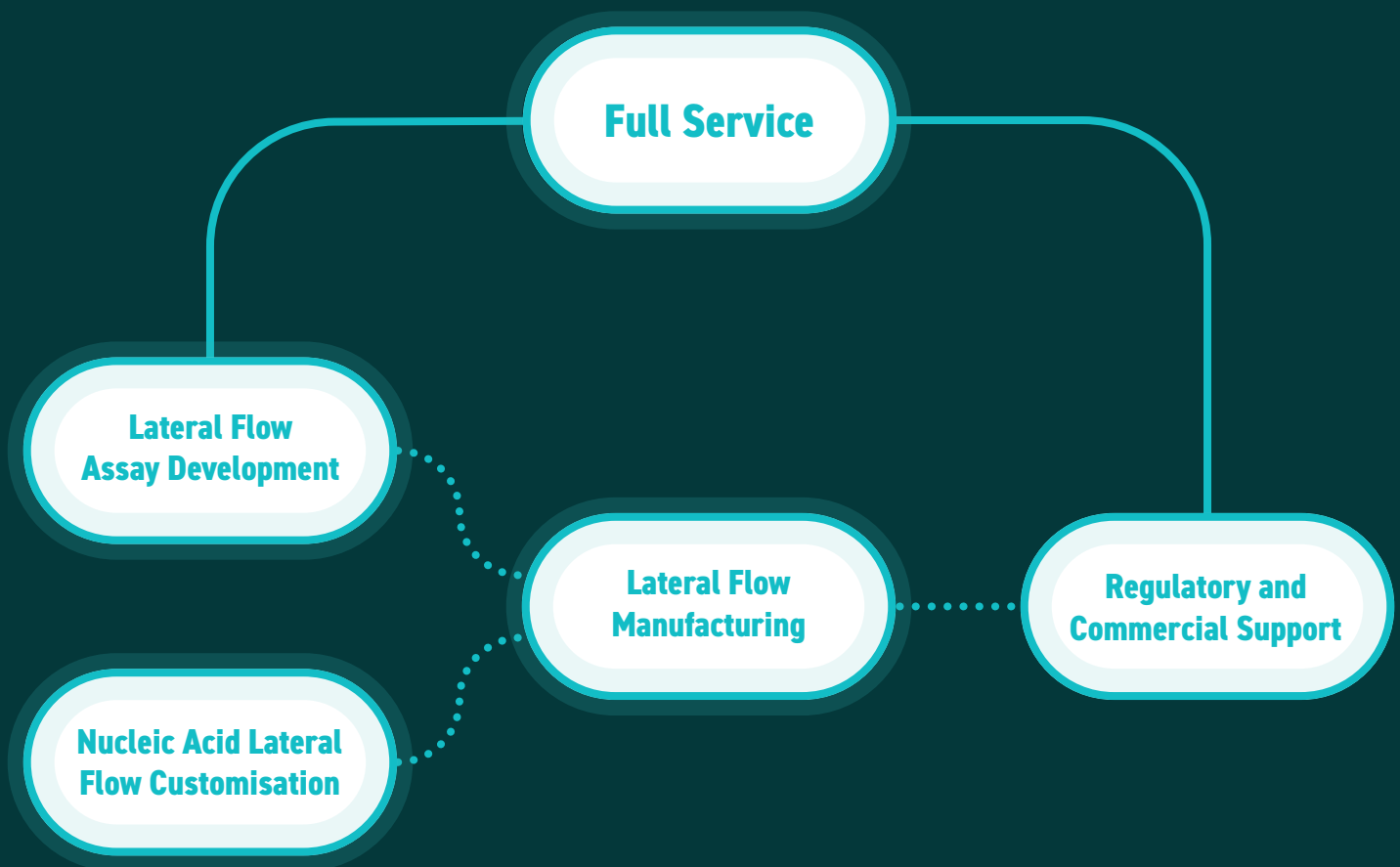
Improving life by making rapid results accessible to all.

Passionate about supporting our clients' lateral flow tests ambitions, now and in the future.

Abingdon Health combines lateral flow experience, precision technologies and a robust supply chain to deliver outsourced rapid test solutions that offer customers long-term support throughout the product life-cycle.

From initial concept, through to scale-up and large-scale manufacture, and combined with commercial and regulatory support, Abingdon Health's services are a de-risked approach for ensuring the consistent supply of reliable rapid tests.

OUR SERVICES INCLUDE:



- Certified to ISO 9001 and ISO 13485
- Compliant to FDA 21 CFR 820 and GMP
- Meets regulatory requirements of UK MDR 2002, IVDD 98/79/EC and IVDR 2017/746
- Establishment registration with the FDA

Rapid test contract development

As specialists in our field, we provide depth of experience and technical knowledge to ensure the smooth transition from lateral flow test development into reliable manufacture.

- Quality material selection and application
- Experience with multiple assay formats and sample matrices
- Robust test specifications with manufacture in mind



Rapid test contract manufacturing

With many years of experience and the latest lateral flow manufacturing technologies, we assure the consistent production of quality tests, on-time and in-full (OTIF).

We offer flexible and scalable solutions to meet the different and changing needs of a diverse client base, no matter the complexity of the test or market.

- Part or full manufacturing solutions
- Adaptability and contingency planning for disaster recovery and coping with spikes in demand
- A de-risked service underpinned by an established supply chain
- Regulatory and commercial support for smooth market entry and increasing reach



Contain Risks And Embrace Opportunities

Partnering with Abingdon Health gives you exclusive access to our dedicated and friendly team, and experience gained through the delivery of multiple development and manufacturing projects across many industries.

PARTNERING WITH ABINGDON HEALTH ENABLES:

- Stable long-term pricing models to support your budget, business planning and hitting goals
- Established processes and procedures ensuring the delivery of projects on-time and in-full (OTIF)
- Peace of mind through long-established supply chains and the reliable selection and application of quality materials
- Adaptability and contingency planning in state-of-the-art facilities to cope with spikes in demand
- On-demand access to knowledge from years of experience working with different assay formats and sample matrices
- Full assay product life-cycle support to reassure you at every step of the process
- Support for both regulated and less-regulated markets
- Transparency of your project ensuring you always have complete visibility

Our partner-led approach

RAPID TEST CONTRACT DEVELOPMENT

Abingdon Health uses a comprehensive design control driven approach to assay development that includes:

- Detailed project plans with transparent and easy to understand go/no go junctions
- Expert selection of sustainable and quality materials via our robust supply chain
- Regular process updates from your dedicated project managers and technical leads
- Access to in-house experts for regulatory requirements
- Fully documented design history file
- Forward planning to ensure reliable manufacture



TEST FORMATS INCLUDE:

- Qualitative
- Quantitative
- Semi- quantitative
- Single-target
- Multiplexed

RANGE OF SAMPLE MATRICES INCLUDE:

- Saliva
- Serum
- Plasma
- Whole blood
- Urine
- Food and beverages
- Plant material and soil
- Water
- Fuel
- Veterinary samples

TRANSFER TO SCALE-UP AND MANUFACTURE

Following assay development with Abingdon Health or transferring a test from a third-party, our transfer process includes:

- Assessment of assay performance and materials
- Review and establish clear manufacturing protocol
- Scale-up and transition to required volumes
- Forward scale-up plan, if required

RAPID TEST CONTRACT MANUFACTURING

Low, medium and high-volume manufacturing solutions throughout your product's life-cycle.

- Flexible full or part manufacturing solutions to meet diverse needs
- Transfer new and existing manufacturing Standard Operating Procedures into routine manufacture
- Troubleshoot test performance and optimise test recipes and specifications
- Scale-up from bench to automated manufacture
- Scalable solutions in line with growth plans
- Adaptability in response to spikes in demand
- International shipping and supply chain management
- Regulatory and commercial support

LONG-TERM VALUE ADDED SERVICES

Abingdon Health is proud of being approachable and values its long-term customer-partnerships. We see ourselves as an extension of our clients' team and enthusiastically support them to navigate regulatory and commercial barriers when launching products or reaching new territories.

Next Steps

Speak to a member of our team to discuss your lateral flow requirements in confidence:

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ABINGDON
HEALTH



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