



ABINGDON
HEALTH



Flexible and Scalable Lateral Flow Test Contract Manufacturing

Outsource with experts to support
your product's growth

Abingdon Health combines many years of experience with a multi-disciplinary, partner-led approach to deliver low to high volume manufacturing solutions that are customised to your needs.

The benefits of outsourcing your lateral flow manufacturing with Abingdon Health.

- **Automated manufacturing equipment** adaptable to different assay formats and volume needs.
- **Precision** underpinned by in-process ISO-led quality control, providing robust and reliable products.
- **Multiple manufacturing lines** to serve routine manufacturing as well as unexpected spikes in demand.
- **Strong and long-term established supplier network** for an uninterrupted supply chain.
- **Access to our in-house highly skilled and experienced team** of development, technical transfer and lateral flow manufacturing experts who will support your product through its full life-cycle.
- **Ensure market entry and accelerate your reach** with access to regulatory support and established commercial channels.
- **Boost competitiveness** through in-depth experience, technical knowledge and market insights, enabling you to identify new opportunities and adopt new technologies more quickly and profitably than competitors.

Abingdon Health's manufacturing capabilities:

- Low to high-volume batch sizes
- Automated and semi-automated manufacturing
- Adaptable manufacturing equipment to fit every individual product need
- Technical expertise in all aspects of lateral flow test formats, critical reagents and materials
- Established international supply chain and logistics solutions
- Packaging for regulated and less regulated markets
- Certified to ISO 13485 and ISO 9001
- 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

Abingdon Health acts as an integral strategic component of our clients' overall strategy. Allowing focus on wider business goals and providing a de-risked operational partnership:

- Smooth assay transfer from third-party development or manufacturing suppliers
- On-demand access to state-of-the-art lateral flow technology that enables continuous improvement capabilities
- Consistent quality control and materials management to ensure long-term robustness
- Option for Abingdon Health to adopt legal manufacturer status of your assay
- Regulatory and compliance support from our specialist in-house team



A glimpse at our technical transfer process:

- 01 **Step 1**
Initial scoping discussion and planning concerning your lateral flow requirements, including:
 - Batch sizes
 - Manufacturing forecasts
 - Packaging design and requirements
 - Labelling
 - Regulatory needs
- 02 **Step 2**
Stability testing protocols agreed with field trials and shipping studies undertaken.
- 03 **Step 3**
Formulation of documents for regulatory, procedural and production staff training requirements.
- 04 **Step 4**
Reproducibility and robustness assessment during production scale-up.
- 05 **Step 5**
Your project team will establish a timetable of manufacturing protocols and deliverables.
- 06 **Step 6**
Preparation of process validation batches.
- 07 **Step 7**
Your lateral flow rapid test is ready to be deployed and scaled-up into routine manufacture.
- 08 **Step 8**
Your project manager will keep you updated with continuous progress updates.

Long-term support throughout the product life-cycle

We are committed to long-term partnerships and offer specialist skills in development, manufacturing, regulatory and compliance, and commercialisation, to help ensure our clients achieve their goals.

Our dedicated project team advise on next generation developments, provide continuous improvement plans and support go-to market strategies for both new tests and lateral flow devices already on the market.

We look beyond our contract services to comprehensively understand how best to support growth opportunities for our customers' test(s) now and in the future.



Second source manufacturing and extending your reach

Through Abingdon Health's capacity and capabilities, we are able to support our clients existing manufacturing solutions to either plug a gap in meeting existing demand or to cope with an increase in demand.

Having access to our manufacturing resources ensures clients not only meet their end users' needs, but also provides reassurance when the business is faced with unexpected spikes in demand, such as seasonal or outbreak requirements.

Scaling up your production for all scenarios

With our automated manufacturing equipment located across two sites, tried and tested processes and people are already in place. Providing the capacity and capabilities to flexibly ramp-up production quickly and at scale to fulfil unexpected demands.

Our dedicated project team provide constant detail on peak production volumes and materials management processes, providing reassurance and transparency that rapid tests will be made on-time and in-full (OTIF).



A safe pair of hands

We believe that the most trusted outsourcing manufacturers form long lasting partnerships with their clients, and as such are often considered an extension of the clients' in-house teams.

The right outsourcing partner feels like a safe pair of hands, and with our agile and trustworthy team, we deliver rapid tests that are robust and reliable, time after time.

Next Steps

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

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Improving life by making rapid results accessible to all.
