



ABINGDON
HEALTH

RAPID
DIAGNOSTIC
TECHNOLOGIES

Near-patient testing: helping guide patient therapy pathways



Bringing therapeutics closer to the patient

ISO 13485 ISO 9001

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Lateral flow rapid diagnostics: an invaluable tool for aiding therapeutics and critical care pathways

Monitoring patient response to therapeutics comes with a need to follow certain assessment and testing protocols. Conventional central laboratory testing programs can be lengthy, possibly causing anxiety for patients and unnecessarily using up vital funds.

Deploying simple lateral flow immunoassays and using Smartphone technology to record and transmit results offers a cost-effective patient centric approach. Tests can be performed at Doctors' offices or at home, and results can be presented in minutes.

Diagnostic testing linked with pharmaceutical therapies and vaccines is increasing as public and private health budget managers seek to demonstrate the efficacy and value of chosen therapies.



Point of Care (POC) testing and Smartphone Apps: an ideal solution

Whether seeking to demonstrate drug efficacy, decentralise clinical trials, manage drug adherence programs or support over-the-counter (OTC) therapies, point of care tests combined with Smartphone readers offer significant benefits to the patient, clinician and pharmaceutical provider.

The benefits:

- Faster decision making
- Cost-effective monitoring of patient response in a timely and efficient manner
- Reduced clinic visits with home testing and OTC options
- Simple data management solutions through hand held and Smartphone readers
- Apps can collect and transfer data from multiple connected locations
- Widen screening programs or increase frequency of testing for chronic conditions or drug adherence programs
- Therapeutic product differentiation
- Improving end-user-experience
- Providing continuity of contact with patients over geographic distance

Adopting these technologies is straightforward owing to an array of features:

- Easy user systems requiring minimal training
- Intuitive instructions within Apps to aid correct deployment for professional or home testing
- Cloud connectivity to a central database from multiple locations
- Geographic record and date stamping of test-use for traceability and epidemiology
- Visual record of test for historical reference
- Consecutive, multi-line read allowing multiplex solutions to be read in simple format

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Abingdon Health's approach to near-patient test development

Abingdon Health's pedigree in lateral flow development and ability to assume legal manufacturer status on behalf of its customers expedites the development, manufacture and launch of a near-patient test. This presents a time and cost-efficient route to market and a long term assurance of post launch product support and continuity of supply.

Abingdon Health can support you in these areas:

Providing regulatory and commercial support:

- Adoption of legal manufacturer responsibilities and regulatory support in order to facilitate and expedite market entry.
- Regulatory submissions from an experienced in-house team that has registered assays and readers in a number of territories.

End-to-end development services:

- Ability to develop tests for a variety of markers found in varied sample matrices.
- Established processes and procedures to source reagents and develop to challenging targets and performance requirements.
- A seamless process through test development, transfer to manufacturing, launch and commercialisation.

Manufacturing:

- Scalable manufacturing solutions from transfer and validation through to large batch production with automated, semi-automated and manual solutions deployed as appropriate.
- Design Control and material management to ensure test robustness and peace of mind in the long-term.

Commercialisation:

- Significant post launch experience
- Advice under contract or directly undertake the activities as the legal manufacturer.

Compliance:

- ISO 13485:2016
- ISO 9001:2015
- GMP standards

Abingdon Health's Services:

- ✓ Reagent sourcing
- ✓ Assay development
- ✓ Manufacturing
- ✓ AppDx Smartphone Reader platform customisation
- ✓ Legal manufacture status and regulatory support

Learn more

Visit abingdonhealth.com/contract-services to learn more about our services and abingdonhealth.com/lateral-flow-immunoassay to learn more about lateral flow technology.

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Bringing therapeutics closer to the patient

Configuring a near-patient test to detect drug activity markers

The following describes how Abingdon Health develops near-patient tests for the pharmaceutical industry.

- Phase 1:** **Initial discussion and planning** concerning materials, end-user needs, sample types, regulatory requirements and device specifications.
- Phase 2:** **Feasibility and optimisation** of device specifications, user protocols and sample collection.
- Phase 3:** **Transfer to manufacturing** for high throughout automation.
- Phase 4:** **Regulatory assistance** with submissions and the clinical trial process.
- Phase 5:** **Routine manufacture** in-line with agreed batch sizes and in packaging that meets regulatory requirements.

- ✓ Experience of working with pharmaceutical companies
- ✓ Significant understanding of end-user and market needs
- ✓ Legal manufacturer with regulatory experience
- ✓ Quality focused – ISO 13485, ISO 9001, GMP, FDA, CE
- ✓ Experience of working with a range of biomarkers
- ✓ Capacity to meet high-volume demand
- ✓ Leading edge reader technology solutions
- ✓ Flexible and pragmatic approach

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