

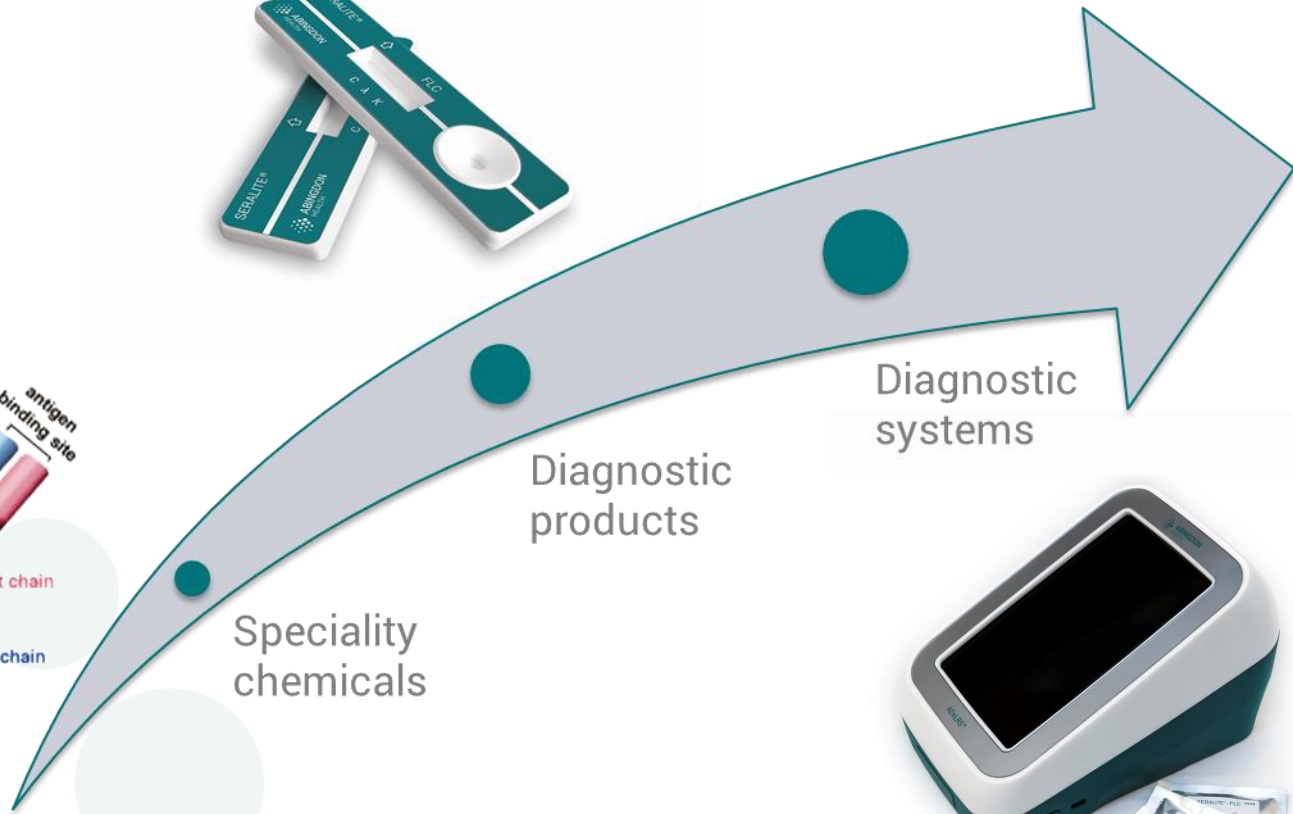
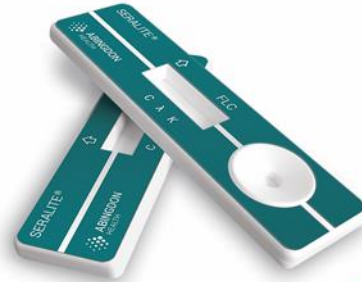
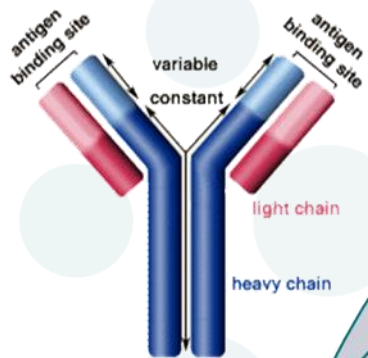
# Introduction to Abingdon Health

# Abingdon Health Snapshot

- Fully integrated lateral flow (immunoassay) diagnostic company
- Contract development and manufacture of lateral flow assays and readers across a range of sectors including clinical, animal health, agri-food and environmental
- Experienced management team with over 100 years of combined diagnostic experience at, inter alia, Siemens, Danaher, Alere, Axis Shield, IDS and Cozart
- Quality focused company
  - ISO 9001:2015
  - ISO 13485:2016
  - GMP compliant manufacturing facilities
  - FDA registered lateral flow reader



# Lateral Flow Expertise



Diagnostic systems

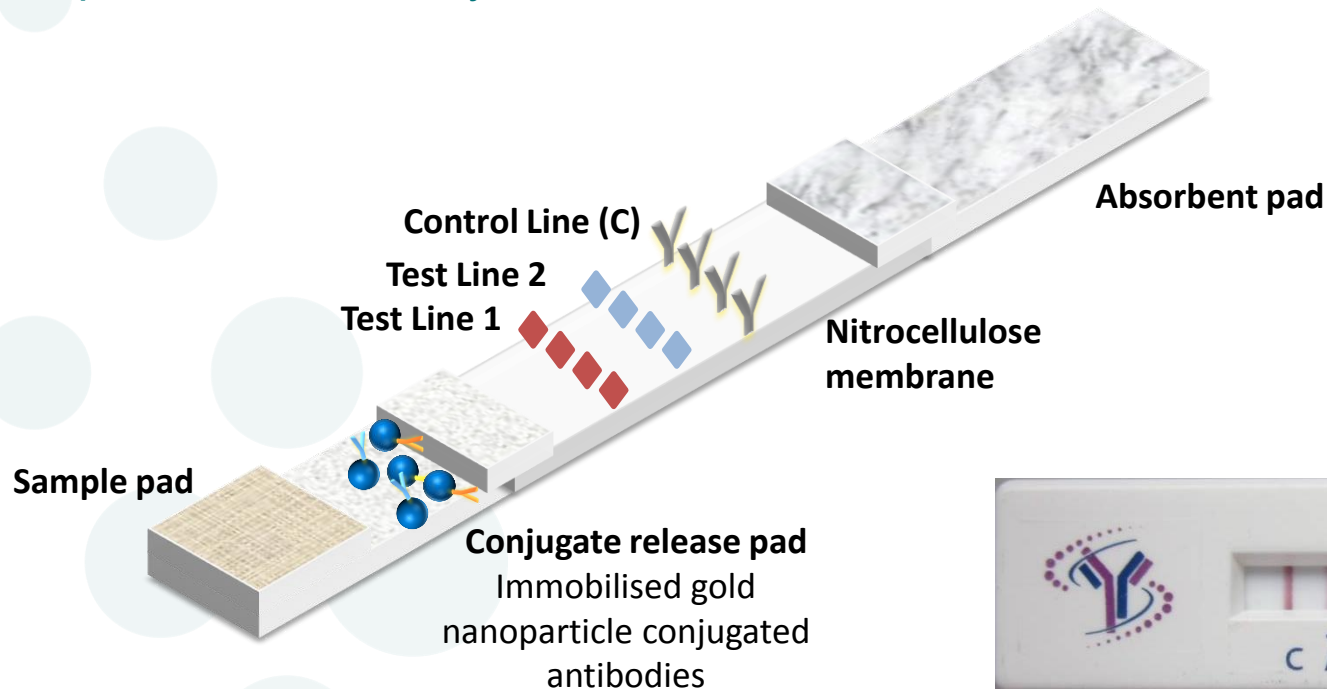
Diagnostic products

Speciality chemicals



# Flexible Diagnostic Technology

- Single biomarker or multiplex capability
- Qualitative or quantitative
- Competitive or sandwich assay format
- Gold, latex, carbon, polystyrene bead, fluorescent labels
- Dipstick or cassette style device



# Proven Track Record - All Market Sectors

## ➤ Contract Services

- Over 150 projects completed including grant funded and commercial ventures
- Experience with wide range of matrices including whole-blood, serum, saliva, urine, milk, tissue, faeces, food and feed products
- Products in manufacture for animal health, human health, agri-food, and environmental sectors

## ➤ Seralite-FLC<sup>®</sup> – Diagnosis and monitoring tool for multiple myeloma patients

- Idea to market in 3 years
- Fully quantitative assay developed from concept using proprietary antibodies
- Used in combination with FDA registered ADxLR5<sup>®</sup> reader
- CE marked product, with product registration in over 70 countries

## ➤ Pocket Diagnostic<sup>®</sup> - Plant pathogen product range

- Qualitative assays for in-field use – government agencies, agronomists, farmers
- Distributed worldwide for over 10 yrs

# Comprehensive Service Offering

- Lateral flow device assay design and development
- High throughput manufacturing
- Reader design and development
- Commercialisation & launch



Concept & Planning



Reagent Sourcing



Feasibility & Optimisation



Transfer to Manufacture



Routine Manufacture



Reader Design

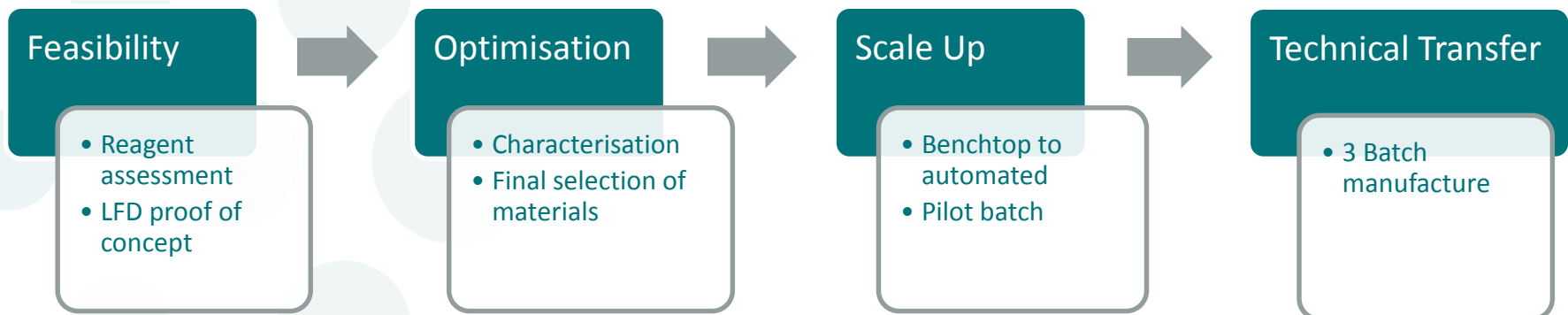
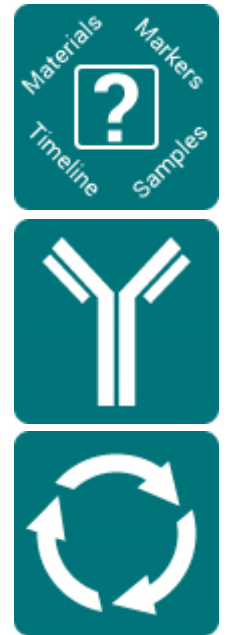


## Lateral flow device assay design and development

- Develop from concept – source or develop reagents for required biomarker
- Transfer validated reagents – owned or sourced by customer
- ELISA transfer – conversion of an existing ELISA assay

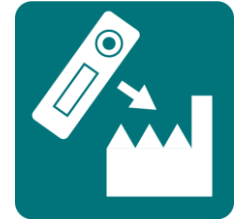
Initial priority to establish market requirements, product specifications, and regulatory considerations.

A product development plan outlines the key phases required to take the product to manufacture.



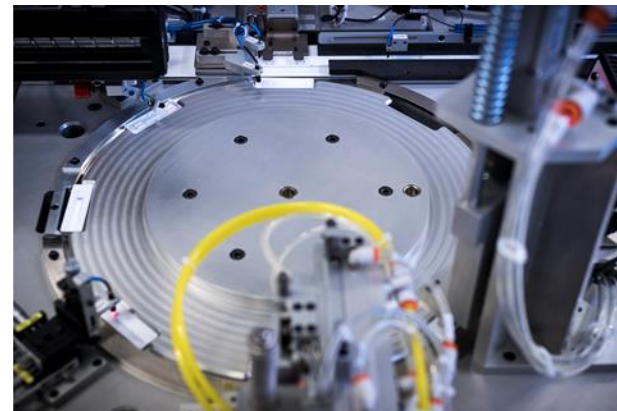
# High Throughput Manufacturing

- Scale up and transfer from assay development
- Technical transfer from existing manufacturer



State of the art environmentally controlled manufacturing facilities with fully automated production capabilities including:

- Reel-to-reel web handling system for reagent spraying
- Auto-laminator for assembly of membranes and other components
- Automated dispensing of buffers
- Device assembly
- Kit packaging





# Market Leading Reader Technology

## Reader design and development

- ADxLR5® benchtop reader – OEM customisation
  - As part of LFD assay development package
  - Adapt for existing devices on the market
- Handheld reader – OEM customisation provided by Skannex



## ADxLR5® Specifications

- CE marked, FDA registered
- Colourimetric based detection
- Quantitative, semi-quantitative or qualitative read out
- Single or multiple biomarker compatible, single, double or triple strip format
- Full connectivity for seamless data transfer (Wi-Fi, USB or Ethernet connection)
- 10.1" Touch Screen Interface
- Data storage greater than 10,000 results
- Gold, latex, polystyrene beads, carbon label compatible

# AppDx – Smartphone reader

- Suitable for qualitative and semi-quantitative LFDs
- Compatible with both Android and Apple platforms
- Full OEM customisation including:
  - ✓ Set data criteria i.e. testing locations, times and dates
  - ✓ Set access criteria for viewing data
  - ✓ Define how data results are displayed



# Commercialisation Expertise

Building on our experience of commercialising our own diagnostic products we can offer assistance with various aspects of commercialisation and product launch.

- Quality and regulatory guidance
  - FDA
  - CE
- Product packaging solutions
- Product insert (IFU and Manuals) assistance
- Assistance with marketing plan
  - Preparation of marketing materials
  - Communication with KOLs
  - Social Media
- Identification of distribution partners
- Supporting contract negotiation
- Logistics solutions



# How Abingdon Health Can Support You

- We are customer focused with an emphasis on building long term business relationships
- Assay development team has broad assay experience across a range of biomarkers and industry sectors
- Automated facility for high throughput manufacture
- Quality focused – ISO13485, ISO9001, GMP, FDA, CE
- Leading edge reader technology solutions
- Flexible, pragmatic and cost conscious approach to your lateral flow needs



Any Questions?

# Appendix - Videos

Manufacturing video - <https://youtu.be/MM71zLzaSxE>

Technical transfer and scale up video - <https://youtu.be/VtkFSmj1U74>

Reader OEM - [https://youtu.be/Ro6w-55\\_q04](https://youtu.be/Ro6w-55_q04)

