

Demonstrating the impact of PSRE: Forsite Diagnostics

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Agenda

Forsite Diagnostics is a commercial spin out from the Food and Environment Research Agency (formerly CSL)

- brief introduction to Forsite
- challenges to spin out Forsite
- direct and indirect PSRE impact

Who are Forsite?

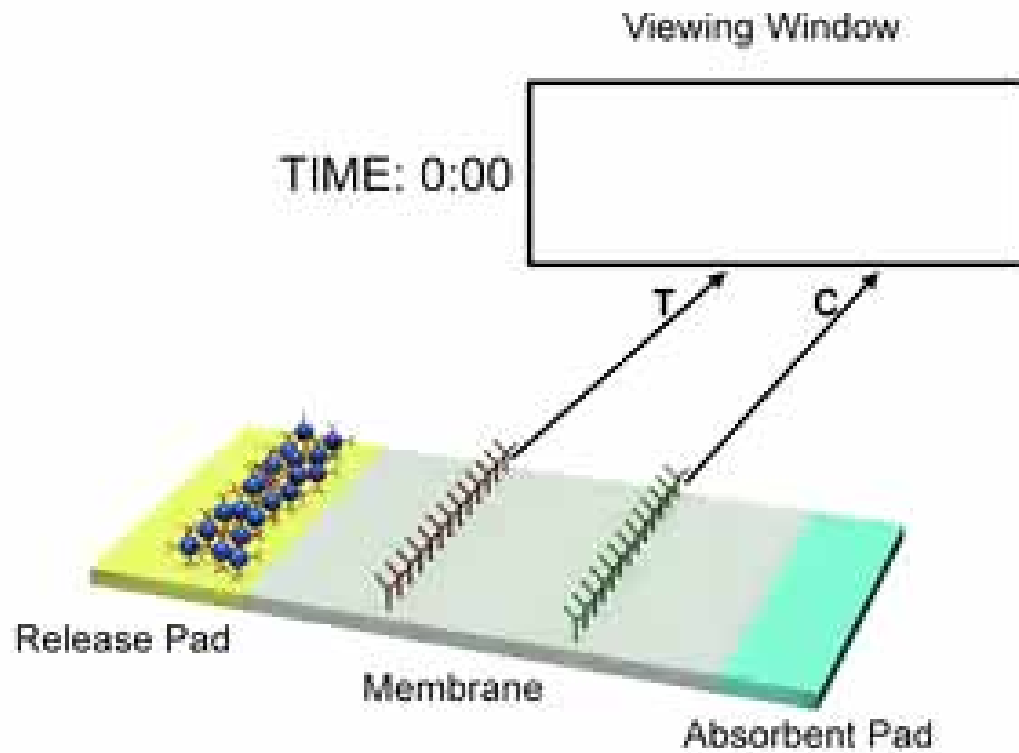
- focused entirely on contract development and manufacture of lateral flow tests
- spin out from Central Science Laboratory in January 2007, with private sector investment
- parent company is Safeguard Biosystems, which has interests in veterinary diagnostics
- FERA retain 24% equity, 10% for transferring staff, Safeguard remaining 66% majority
- active in plant health, animal health and food safety and human 'well-being'

The Lateral Flow Test

- simple to use
- inexpensive
- rapid
- reliable
- sensitive
- for on-site use
- massive uses worldwide

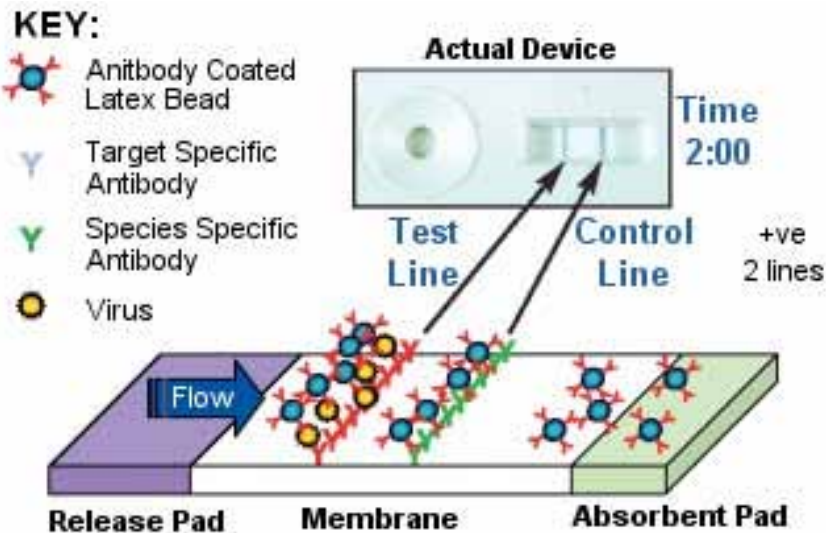


Animation

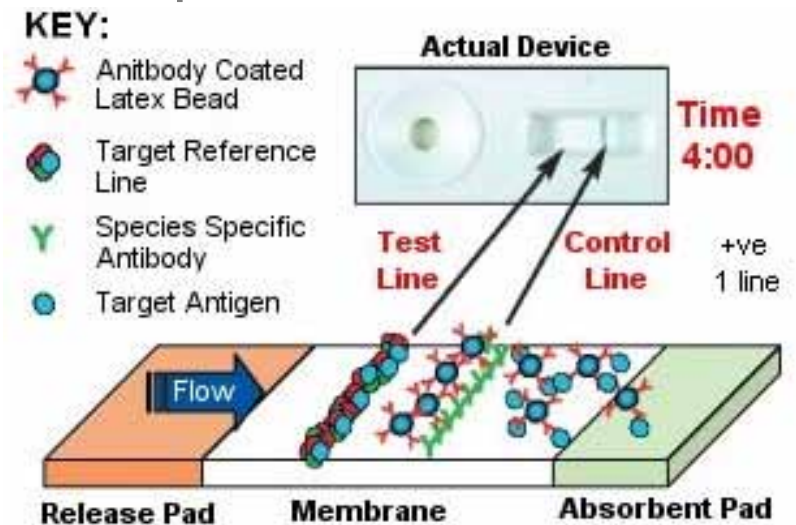


LFD Formats

- Sandwich assay
- Licence required in US only since April 2008
- Pathogen detection
- Traditional 2 line positive result



- Competitive assay
- No patent encumbrances
- Target molecule detection
- Lends itself to semi-quantitative measurement
- 1 line positive result



Modern facilities

- 12 staff in R&D, production and marketing
- located within the secure government site (Fera)
- modern equipment for manufacturing LFDs
- ISO 9001 standards of operation



Specialist capabilities

- in-house R&D expertise with strong network of international collaboration
- high volume LFD manufacturing capability
- success in taking products to market
- close co-operation with international R&D partners on development of LFD tests



Examples of tests developed

- plant pathogens
- bacterial pathogens
- veterinary diseases
- environmental contaminants
- plant-derived bioactive molecules
- food allergens
- residues in feed
- GM markers
- authenticity markers
- isothermal PCR detectors



Pushing the boundaries

- partner in several EU projects
- pioneering the use of quantitative LFDs and development together with new Reader
- advancing LFDs for use in on-site molecular tests to achieve greater sensitivity and specificity
- alongside utilising unique IP licence for molecular confirmation from LFDs performed in the field



Timescale of technology

- 1996 PH0132 Development of field test Kits (Defra)
- 1999 PH0156 Validation of PVY and PVX (Defra)
- 1999 PH0165 Strategic development of LFDs (Defra)
- 2000 HS25 Competitive LFDs (CSL Seedcorn)
- 2000 Launch of PD Brand
- 2001 Foot & Mouth virus LFD demonstrated
- 2001 Winner of Westminster Medal
- 2001 Bee disease and feed residue LFDs (Commercial)
- 2002 Separate business unit
- 2004 Winner of Venturefest York
- 2005 Patent filed (semi quantitative)
- 2006 Patent filed (NA extraction)
- 2006 Investor presentations short list
- 2006 Contract negotiations
- 2007 January 19th/20th Final negotiation and signing
- 2008 Defra win award partly for use of LFD's in monitoring *P ramorum*
- 2008 PD Plus service launched
- 2009 Runner up Innovation Showcase & Innovator/09
- 2009 Pocket Check in Wyevale stores nationwide

10 years and
over £2m
income from
funding and
sales

Challenges to creating a spin out

- an idea!
 - benefit to defra but to anyone else? funding streams act as indicators
- search for funding
 - gain permission needed first from CSL directors and then defra
 - investor pitches & networking whilst maintaining day job
- professional advice
 - experience and relevant legal and commercial advice is expensive
 - creative deals to pay fees were required
- writing an attractive business plan
 - external plan required external business support fine tune
- commitment of the staff
 - entrepreneurial enthusiasm balanced with giving up permanent job
- incubation of the idea
 - business can be stifled but still exists during this process

Challenges in creating Forsite

- protection of IP
 - continuity agreements, supply agreements, licensing options
 - continued access by Fera through collaboration
- TUPE staff transfer
 - pensions, holidays and maternity balanced with realistic pay offers
 - a range of staff contracts requiring experienced independent HR advice
- incentives for staff
 - IP reward scheme added value to the staff on IP for both transferees and remaining staff , stressful but essential
 - shares and options with lock ins
- value of the deal for defra
 - equity issues; shares and defra; SME status; commercial funders;
- long term prospects
 - rent; service agreements; collaborations; EU proposal benefits
 - adding value without state aid issues arising

Summary: Direct impact of PSRE

- Fera/Defra support ongoing commitment
- ideal incubator of ideas and environment to nurture business strategies
- technologies based on 'competitively' funded research
- potential customer for spin out services and products
- intellectual assets valued and supported to encourage entrepreneurial spirit

Summary: Indirect impact of PSRE

- ongoing source of collaboration and information on technical advances
- useful networking opportunities
- access to facilities
- access to expertise
- business strategies employed often mirror those developed within the PSRE before exploitation
- however critical to blend, evolve and stand on own feet

Thank you

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