CSIR research, development and innovation initiatives for the medical device and diagnostic industry

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IDEAS THAT WORK FOR INDUSTRIAL DEVELOPMENT

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Outline

- Overview of South Africa's medical device industry
- Challenges facing the South Africa's medical device industry
- CSIR medical devices and diagnostics framework
  - Medical devices and diagnostics lifecycle management platform
  - Examples of technology platforms

Overview of SA medical device industry

- Market size is R16.9 billion
- Percentage of health expenditure : 4.2
- Percentage to GDP: 0.4

- 94.2% of products imported
- 0.3% of the global market

- Employs over 20 000

- ~30 multinationals companies
- ~ 26 local manufacturers
- Employ less than 50 people

Challenges facing the SA medical device industry

- Lack of infrastructure and skills for research, product design, development, prototyping and manufacturing
- High input costs such material and labour
- Cost of regulatory compliance

As a result R&D and ideas are not translated into products, limiting success of local manufacturers and growth in the medical device sector

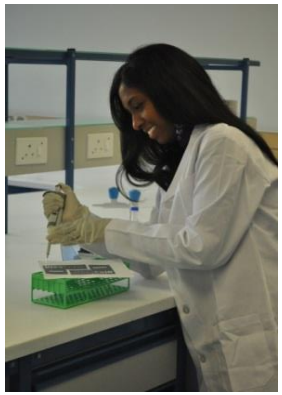
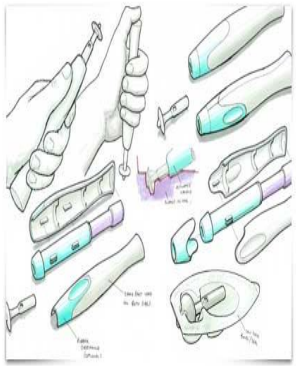
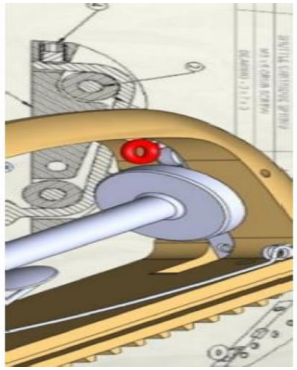
CSIR response:

“Medical Devices and Diagnostics Framework”

Source: *Research to guide the development strategy for the medical devices sector of South Africa, Deloitte 2014*

Addressing the innovation chasm

Technology concepts		Innovation “chasm”			Products
Basic research	Applied research	Product design	Prototype development	Regulatory approval	Manufacturing

Regulatory requirements and compliance

Medical Devices and Diagnostics Framework

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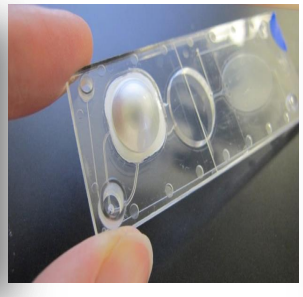
Medical Devices and Diagnostics Lifecycle Management Platform

Material Development	Sensor Development	Product Development	Regulatory Compliance	Manufacturing	After sale and support
			ISO 13485		
• Biomaterials • Nano gas • Microsphere	• Nano-Micro • Microfluidics • Photonics • Ultrasonic	• Photonics prototypying facility • Microfluidics laboratory • Ultrasonic facility	• ISO 13485 Certification • CE Mark • FDA Approval	• Photonics prototyping facility • Microfluidics laboratory • Ultrasonic facility	• Device connectivity

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CSIR medical devices and diagnostics lifecycle management platform

Medical devices lifecycle management

Concept and development	Manufacture	Packaging, labeling, advertising and sale	Use and disposal

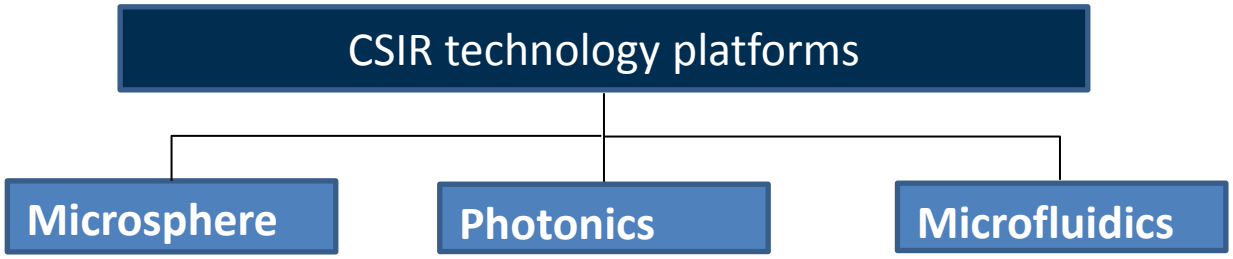
Phases of the lifespan of a medical device

Examples of technology platforms

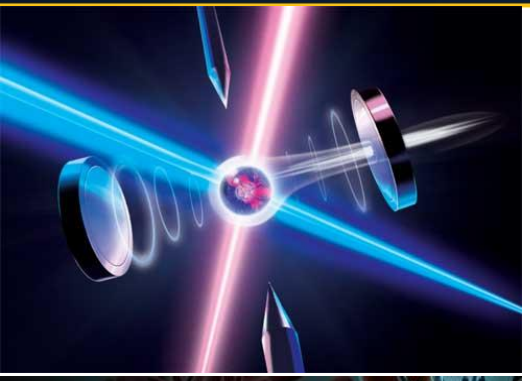
Point-of-care diagnostics

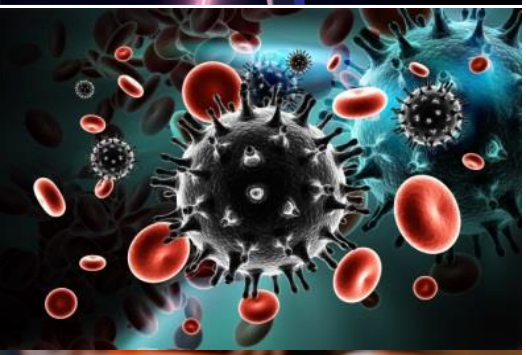
- Point-of-care diagnostics are defined as medical testing at or near the site of patient care
- The aim of point-of-care diagnostics is to provide same-day diagnosis to facilitate immediate decision-making
- The World Health Organisation (WHO) states that diagnostics for the developing world should be ASSURED:

Affordable, Sensitive, Specific, User-friendly, Robust, Equipment free, Deliverable to users (ASSURED)



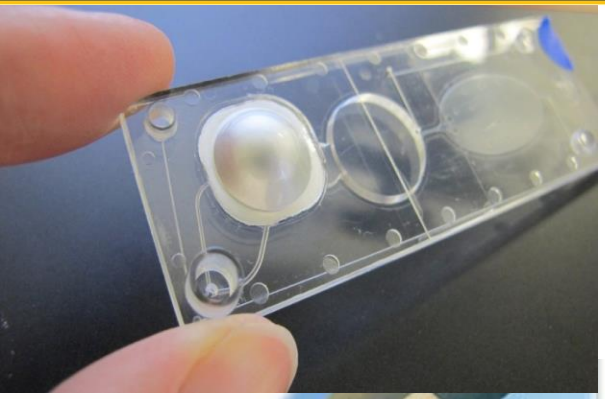
Photonics diagnostics platform

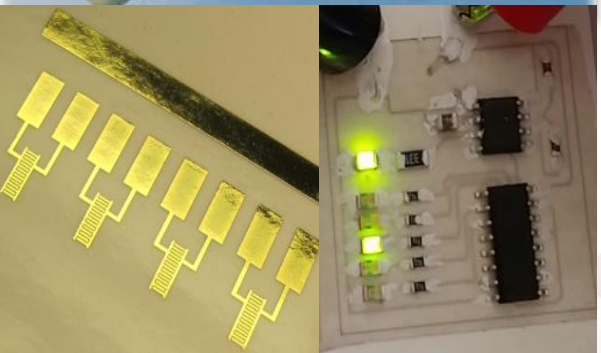




- Aim is to use light to influence and manipulate living systems at cellular, subcellular and molecular level
- The CSIR is well positioned to assist industry to design, develop and manufacture photonic-based point-of-care devices.
- **Advantages**
  - Cost reduction per analysis
  - Portable device, possibly also equipment free
  - Low cost to manufacture and can typically be manufactured at high volume
  - Fulfils WHO Assured principle
- **Example of device**
  - **Ukukhanya** POC to provide rapid HIV viral load testing at the bedside

Microfluidics technology platform

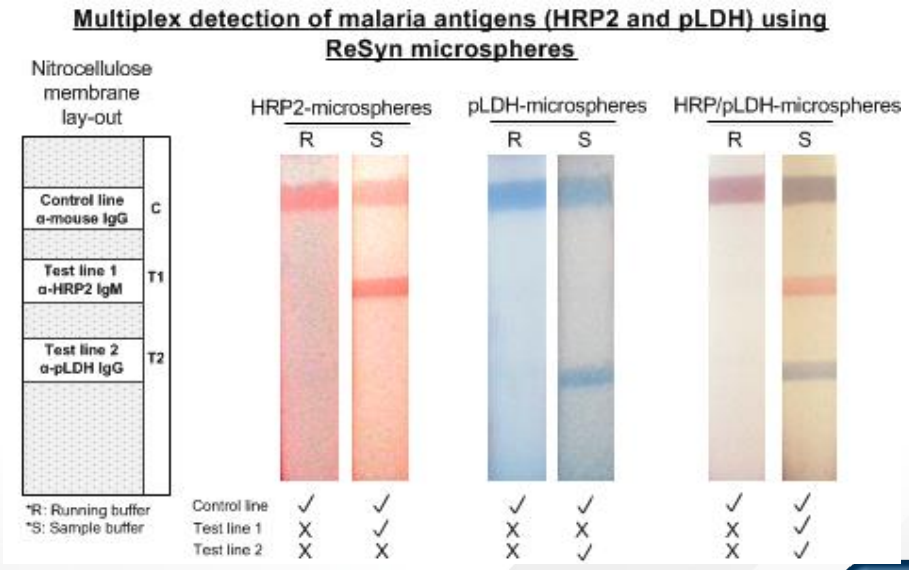




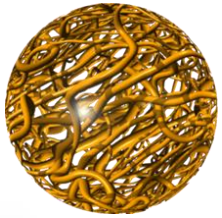
- Microfluidics allow for the precise control of extremely small volumes of fluid.
- The CSIR is well positioned to assist industry to design, manufacture, develop and characterise paper-based and cartridge-based diagnostic devices for applications such as disease diagnostics, drug discovery and blood counting.
- **Value proposition**
  - Development is based on a total system view
  - Device is designed inline with ISO 13485 requirements
  - Microfluidics expertise can be combined with many other areas of expertise within the CSIR
  - Small-scale manufacturing can be done in-house
  - Fulfils WHO Assured principle
- **Example of device**
  - **Cellnostics** device for full blood count analysis

Microsphere technology platform

- Microsphere development for sample preparation, bioseparations, diagnostic, and automated HT screening applications
- Unique, versatile, patented technology platform (ReSyn)
- Licensed to spin-out company: ReSyn Biosciences
  - 15 products; 21 peer-reviewed publications (www.resynbio.com)
  - 1 International award: SLAS 2015 Best New Product Award
- Applications in point-of-care diagnostics



- Improved stability of biomolecules (e.g. antibodies, antigens)
- High specificity (microsphere engineering)
- Multiplexing (various antigens & dyes)



ReSyn Biosciences

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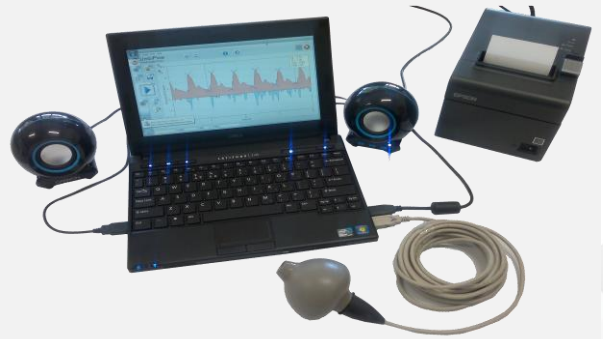
Ultrasonic-based devices



- Use sound waves to view and manipulate the internal body structure such as organ and blood flow
- Design, develop, test and manufacture ultrasonic medical devices primarily for primary care setting
- **Value proposition**
  - Devices can be designed in line with ISO 13485 requirements
  - Small-scale manufacturing can be done in-house
  - Expertise for regulatory requirements and compliance for ultrasound system
- **Examples of devices**
  - **Umbiflow system** for fetal health monitoring
  - **Cardioflow system** for cardiovascular risk assessment

CSIR mandate

The objects of the CSIR are, through **directed** and particularly **multi-disciplinary research** and **technological innovation,** to foster, in the national interest and in fields which in its opinion should receive preference**, industrial and scientific development**, either by itself or **in co-operation with principals from the private or public sectors,** and thereby to contribute to the **improvement of the quality of life** of the people of the Republic, and to perform any other functions that may be assigned to the CSIR by or under this Act."

(Scientific Research Council Act 46 of 1988, amended by Act 71 of 1990)

CSIR is a schedule 3b entity: National Government Business Enterprise

IDEAS THAT WORK FOR INDUSTRIAL DEVELOPMENT

Thank you

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