Development of a rapid molecular POC diagnostic system for STIs

John Clarkson, CEO
Atlas Genetics

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helping you make better decisions

Introduction to Atlas Genetics

- Point-of-Care (POC) molecular diagnostics (MDx) company with focus on infectious disease
- Founded in 2005 and has 41 employees located in Bath, UK and Boston, MA
- Experienced management team
- Raised ~$55 million from blue chip investors

io® System

- Highly differentiated and versatile POC molecular diagnostics platform
- Sample to test result in 30 minutes or less

Blue Chip Investors

NF FUNDED BY NOVARTIS · Johnson & Johnson DEVELOPMENT CORPORATION · CONSORT MEDICAL · BB Biotech Ventures · RusnanoMedInvest · LSP CONNECTING INVESTORS TO INVENTORS

Product Overview
Atlas Genetics **io®** System

Setting the new standard in decentralised molecular diagnostics

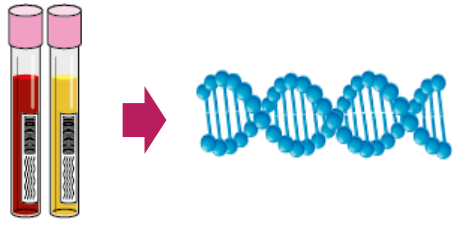
- **Accurate:** Performance equivalent to laboratory systems
- **Fast:** Sample to result in ≤ 30 minutes
- **Easy to use:** Designed for CLIA Waiver. No user intervention following addition of unprocessed specimen on to Cartridge
- **Broad application:** multiplex and multi-sample with up to 24 tests per Cartridge brings extensive menu opportunities
- **Low cost of goods:** Cartridge designed for high volume manufacture

io® cartridge assay process

Combines the sensitivity of PCR with the simplicity of electrochemical detection

1

DNA from the raw specimen is purified



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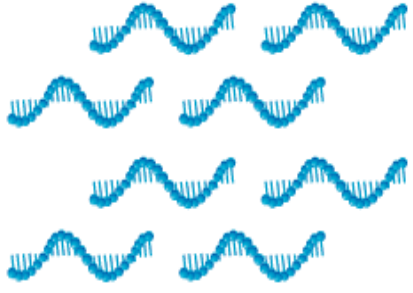
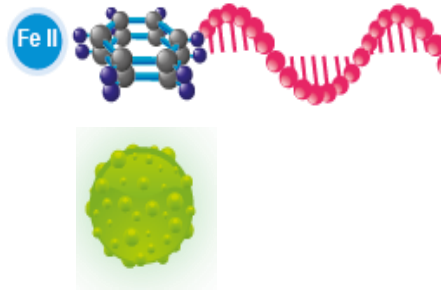
Rapid PCR amplifies target DNA



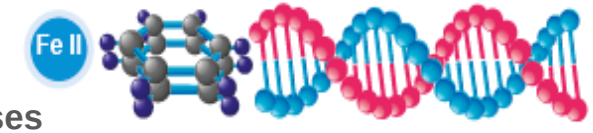
3

Electrochemically-labelled probe & double-strand specific DNA Exonuclease are added to PCR product



4

Electrochemically-labelled probe hybridises to the target DNA



5

Exonuclease digests the target DNA-probe complex, releasing the electrochemical label

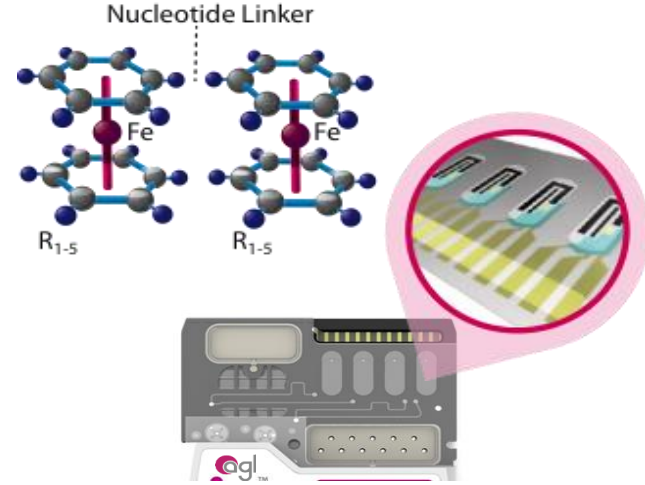
6

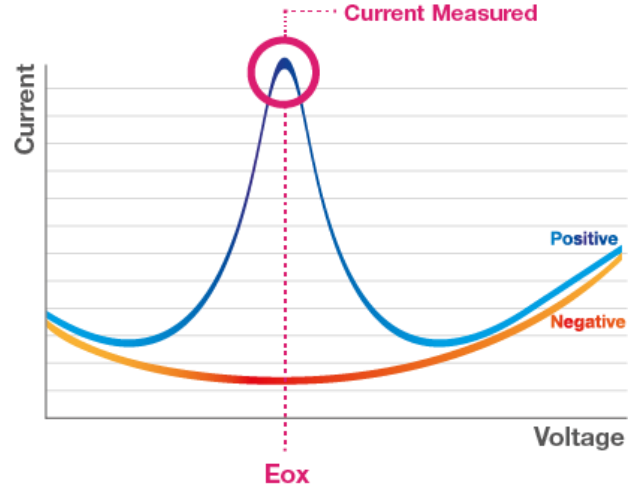
Free electrochemical label is detected using an electrode. The label oxidises at a known potential to produce a current, which is measured

Advantages of Atlas electrochemical detection

Key advantages for electrochemical detection over fluorescence

- **Multi-analytic detection (multiplexing)**
- **Simple, physically robust instrumentation**
- **Ease of miniaturization**
- **No requirement for optical clarity; simpler sample processing**
- **Wide dynamic range**
- **Direct signal output (signal generated and measured as electrical current)**
- **Accepted for diagnostics through widespread use of electrochemical blood glucose meters**





Multiplexing capability
Currently up to 24 tests per cartridge

4 Detection chambers x 6 Labels = 24 targets on 1 patient sample

PCRs 1-12

PCRs 13-24

Det 1

Det 2

Det 3

Det 4

Current

Voltage

Targets 1-6

Targets 7-12

Targets 13-18

Targets 19-24

Sample addition

PCR amplification

Detection

On cartridge fluidics plus electrochemical detection enables multiplex

Clinical performance of CT assay
Lab accuracy at Point-of-Care

Patient #	Sensitivity	Specificity	Predicate Test	Study
275[1]	95.5%	96.8%	BD	St George's University of London
182[2]	94.4%	98.2%	HOLOGIC The Science of Sure	Public Health England
306[3]	98%	98.1%	Roche	JHU CENTER FOR STD POINT OF CARE TESTS

1 Data includes all fresh sample results from formal clinical trial & extended clinical evaluation (submitted for publication by St Georges)
2 Pearce et al (2015) Clinical performance evaluation of a new, rapid point-of-care system for detecting *Chlamydia trachomatis.* ISSTDR
3 Pearce et al (2011) Evaluation of a Novel Electrochemical Detection Method for Chlamydia trachomatis: Application for Point-of-Care Diagnostics. IEE Transactions on Biomedical Engineering 58, 755-758

Manufacturing overview

Established manufacturing partners for leading diagnostics and pharma companies

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io® Instrument

Esterline

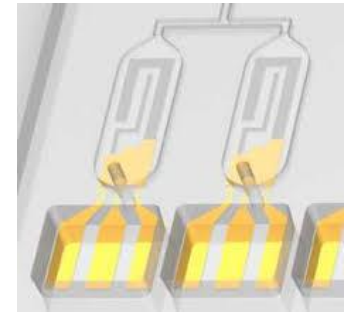
- Assembled by LRE Medical GmbH, a subsidiary of Esterline, in Germany
- Esterline is publicly traded
- CE Marked
- Ample manufacturing capacity

io® Cartridge

CONSORT MEDICAL

- Assembled at Bespak, a subsidiary of Consort Medical, in U.K.
- Consort Medical is publicly traded
- Cartridge designed for volume manufacture
- Injection-moulded components

Reagents



MAKING SENSE OF OUTSOURCING
FleetBioprocessing

- Manufactured at Fleet Bioprocessing in U.K.
  - Capacity: 300,000 cartridges p/a

Future pipeline of STI products
Expanding to higher multiplex tests

Assay development time for each assay of 9-15 months plus clinical trials

CT

- Received CE Mark certification in January 2016

CT/NG

- The first FDA cleared assay for the io® platform will be the CT/NG assay
- Scheduled for launch into the EU markets during the first half of 2017 and into the US market during the second half of 2017

CT/NG/TV

- Multiplex STI (MSTI) will include CT, NG and *Trichomonas vaginalis* (TV)

STI Expansion Menu

- Additional tests planned for the future: CT/NG/TV/MG (MSTI+), NG antibiotic resistant strains, HPV, HSV, HIV

Key Milestones

- Company formed
  - 2005 as a spin out from Osmetech plc (now GenMark Dx)
  - First IP filed 2003 for electrochemical detection of nucleic acids
- Capital raised:
  - 2005 ($1.5m seed)
  - 2007 ($3.5 Series A)
  - 2011 ($30m Series B
  - 2015 ($20m Series C)
- IP
  - US Patent filed 2005; granted 2015
- Clinical studies:
  - JHU study in collaboration with the Center for POC STD tests in 2010; published 2011
  - PHE, London, 2015
  - St Georges, London, 2015
- Regulatory clearance
  - Europe 2016

SECTION

Developing a POC system for STIs

Why did Atlas Genetics decide to develop POC molecular tests for sexually transmitted infections,

and how long did it take?

Is there a commercial opportunity?

- What real medical need is being addressed?
- What is the current market size, value and growth?
- What are the user requirements?
- Is there a trend/demand for decentralisation/POCT? Can this be validated?
  - What are the drivers – for patients, payors and clinicians?
- What will likely pricing be vs cost of goods?
- What investment will be required, over what time, and with what return?

Unmet medical need
Reducing time to treatment

Current Pathway

90% > 4 days[1]

1 2014 audit on UK chlamydia screening turnaround times; US turnaround times typically 4-10 days

Atlas Genetics Pathway

30 minutes or less

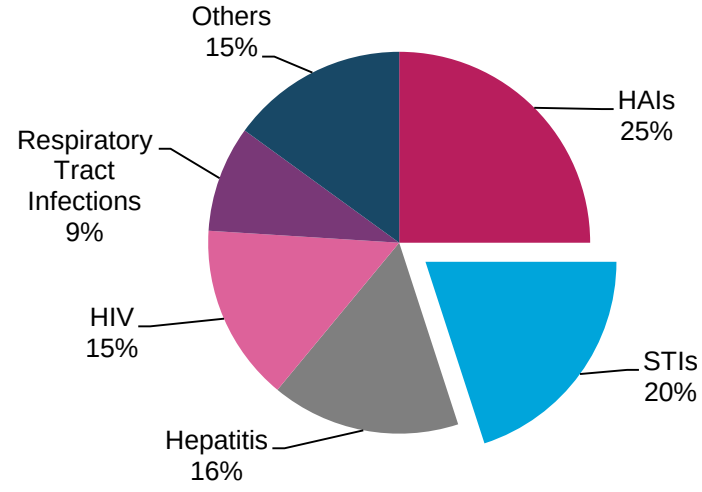
Market size and value
Focus on large and underserved segments

- Market size and growth validated by multiple sources
- No commercially available rapid molecular POC test for STIs in the market today
- Atlas Genetics' platform addresses lack of high accuracy testing with fast turnaround time to drive rapid market adoption

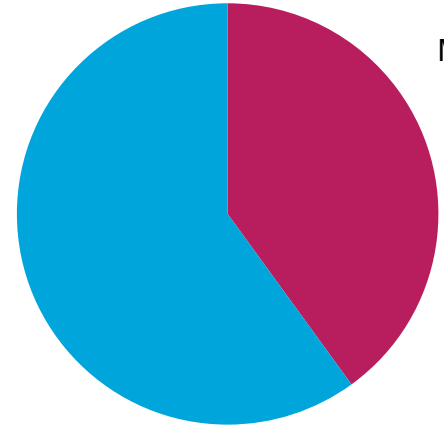
Targeted Customers

- STD Clinics
- Family Planning
- POLs
- Hospital Labs
- Public Health Labs

Global Infectious Diseases Diagnostic Testing by Major Diseases: ~$10bn[1]



Estimated US and EU CT/NG tests: ~67mm[2]



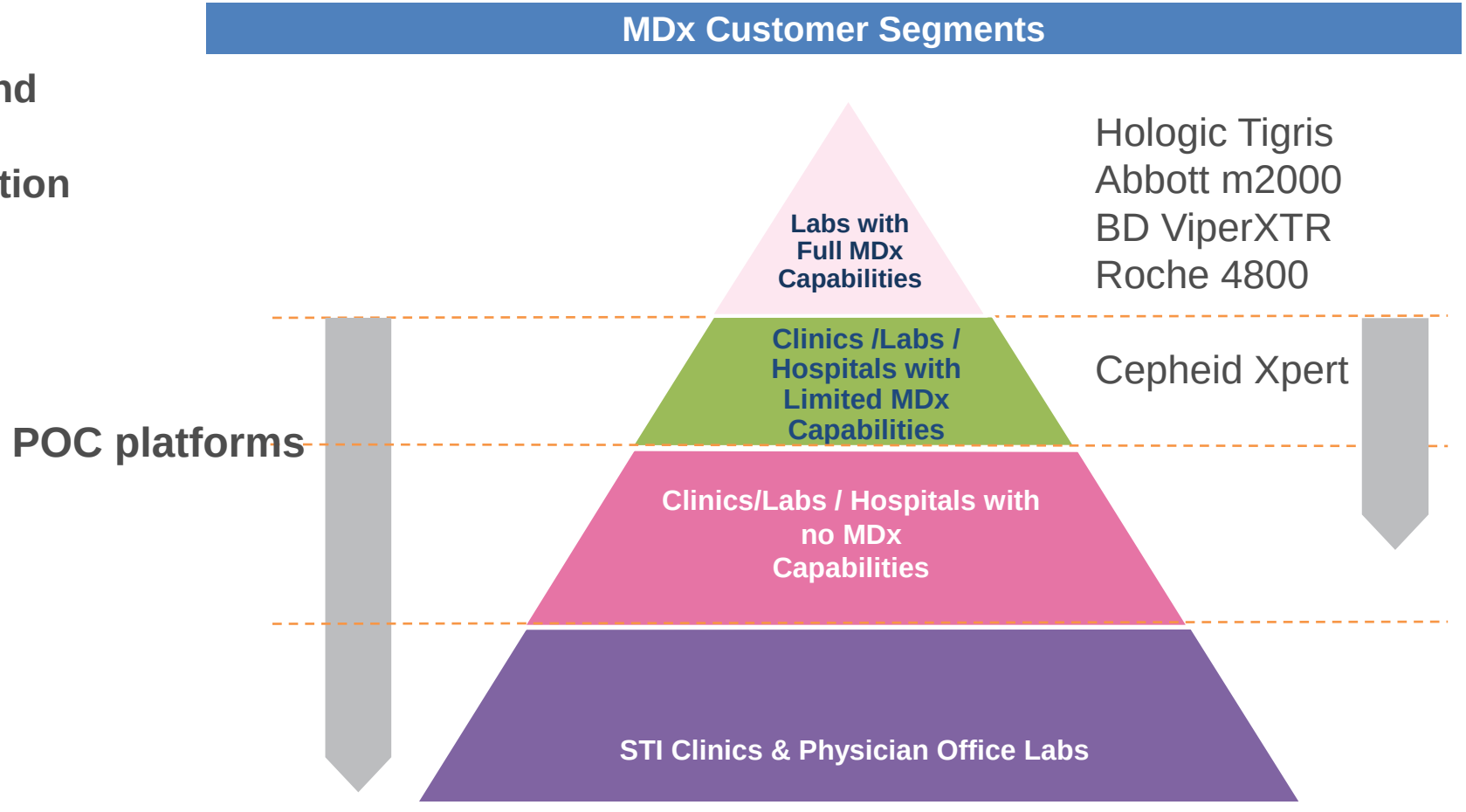
Addressable POC Market Opportunity[3]

40% or ~27mm tests equating to an estimated ~$1bn market opportunity

1 Kalorama November 2015 and Wall Street research
2 CDC data, research analyst's estimates and commissioned market research by LEK
3 Consensus estimate from healthcare industry, research analysts and commissioned market research by LEK

CT/NG testing market today
Concentrated in large hospitals/reference labs

- **Growing trend towards decentralisation**



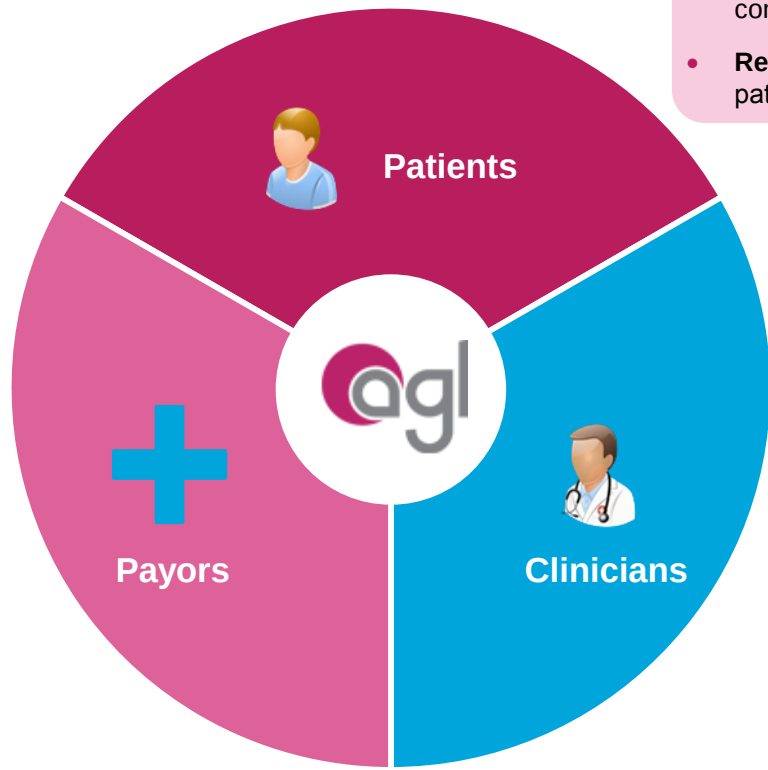
What is required from a POC test?

- Accurate (relative to current practice)
  - CT/NG – central lab tests; Flu A/B – rapid immunoassays?
- Fast (< 30 minutes)
  - Huang et al (2012) 47.5% willing to wait 40 minutes; 28% for 60 mins
- Easy to use
  - must be able to meet CLIA waiver for US market
- Broad application
  - Multiplex and multi-sample
- Provide clinical value
  - measured against current patient pathways
- Affordable
  - measured against current costs and/or reimbursement

What are the drivers

The io system facilitates testing and treatment of patients in one physician visit

- Immediate treatment with right antibiotic, lowering risk of serious complications
- **Reduced physician visits** lowers patient's out-of-pocket cost



- **Lower direct costs of up to 40%**[1] through optimized work-flow
- **Lower long term costs** by reducing disease spread and complications
- Improved antibiotic stewardship – providing "first-line" treatments instead of "last-line" option could **significantly reduce overuse** [2]

- Additional revenue stream with over **US$25/test profit**[3] **to physician**
- Administrative savings from reduced burden of patient follow up **(up to 40% of patients are lost to follow up)**[4]
- Utilize existing reimbursement codes allowing **quick market adoption**[5]
- **Test and Treat** provides better patient management and patient experience

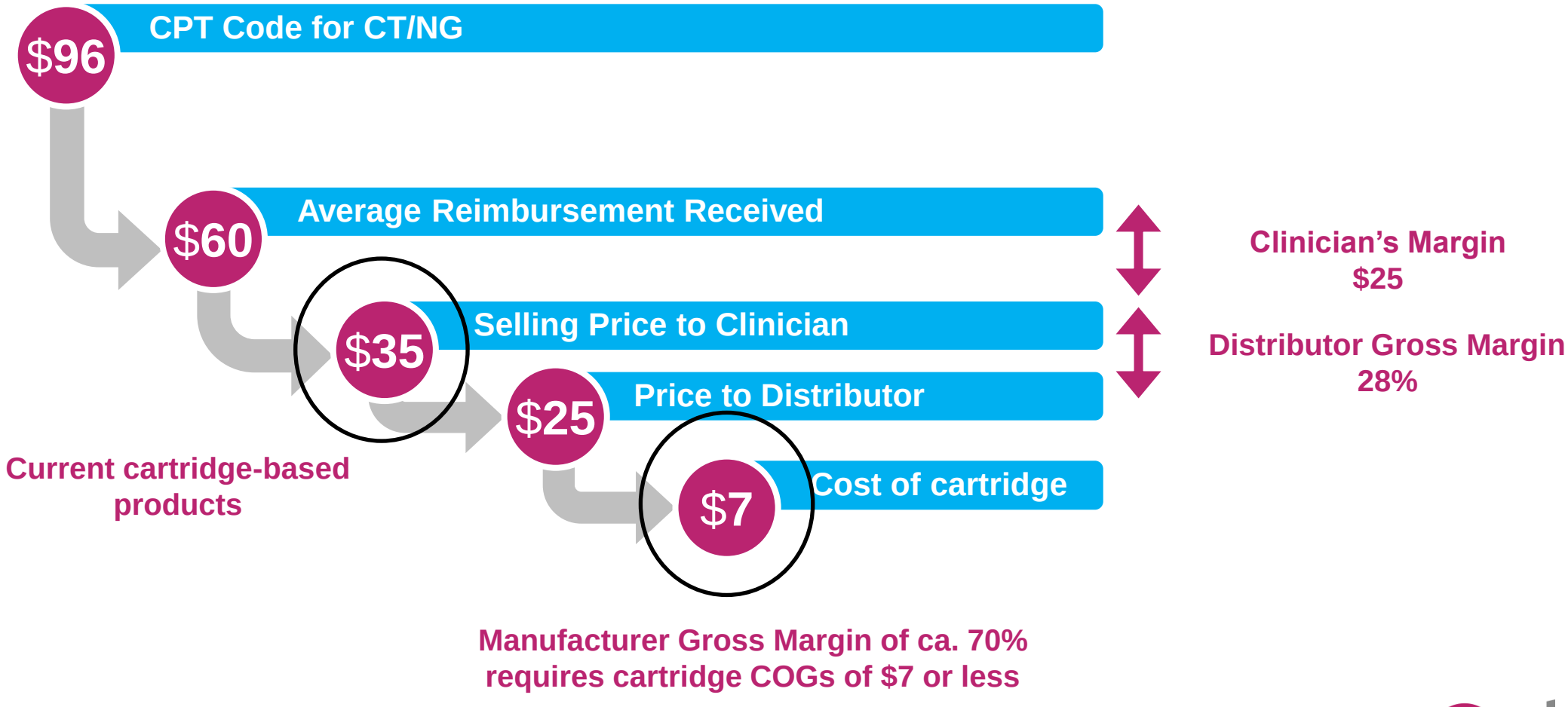
Provides significant value to all stakeholders in the healthcare continuum, including patients, clinicians and payors, which will drive rapid market adoption

1 Adams et al (2014) and Turner et al (2014)
2 The Review on Antimicrobial Resistance, Chaired by Jim O'Neill
3 Profit/test estimate for US physician, based on current reimbursement and product pricing
4 Young Women Often Unreachable After STI Testing, ACEP News by Kerri Wachter (August 2009)
5 Current Procedural Terminology (CPT) code for CT/NG test is 87801

Pricing vs COGs
What gross margin can be achieved?

- Instrument
  - Most customers will not purchase capital equipment
- Cartridge
  - Current CPT code reimbursement for lab molecular tests is ~ $48, or $96 for a combo tests such as CT/NG
    - But average reimbursement is much lower
    - Continued downward pressure on reimbursement e.g. PAMA
  - Most geographies require a compelling business case for the clinician
  - Most POC settings will require a distributor (taking 20-30% margin)

Cartridge pricing
Value Chain for CT/NG in the US



Cartridge Manufacture

- Low Cost of Goods is essential for low/mid-plex POC MDx applications
- Companies must make significant investments in manufacturing to ensure low COGs with consistent quality

What total investment will be required?

And what return will investors make?

- Industry average around $50m for development of POC MDx systems