



**Genetic Signatures**

ASX: GSS

**INVESTOR PRESENTATION**

**AUGUST 2018**

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## REVENUE STAGE HEALTHCARE COMPANY LISTED ON THE ASX

### Genetic Signatures Limited (ASX: GSS)

*A specialist molecular diagnostics company*

- Focused on becoming a global leader in the supply of molecular diagnostic solutions
- Developing and commercialisation its proprietary platform technology, **3base™**
- Implementing its commercial strategy through a team of 30+ across Australia, Europe and North America

### Financial information

Share price (14-Aug-18)	A\$0.580
Shares on issue	103.9m <sup>1</sup>

### Market capitalisation **A\$60.3m**

Cash (30-Jun-18)	A\$9.0m
Debt (30-Jun-18)	Nil

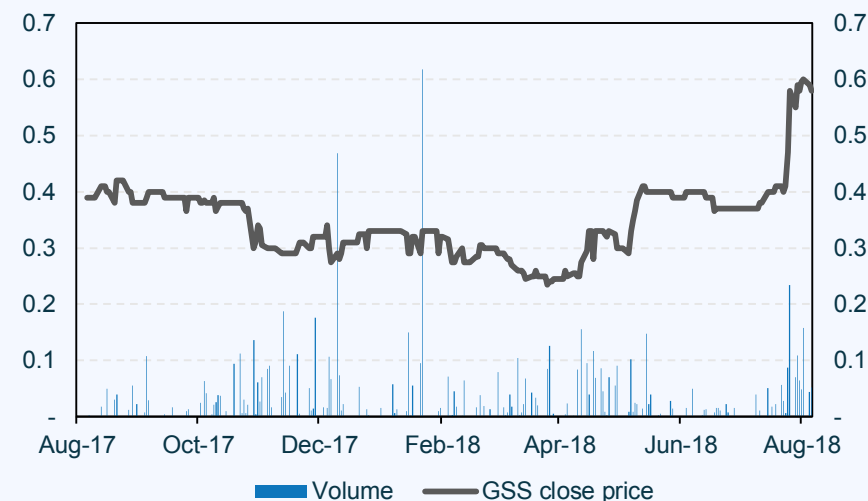
### Enterprise value **A\$51.3m**

Notes:

1: Excludes 1.05m unquoted options (various expiration dates and prices)

### Share price (A\$)

### Volume (m)



### Top shareholders

	%
Asia Union and Christopher Abbott	39.6
Deutsche Bank AG	14.2
Directors, management & advisors	>6.0

## **GENETIC SIGNATURES DEVELOPS AND MANUFACTURES MOLECULAR DIAGNOSTICS KITS BASED ON ITS PROPRIETARY 3BASE™ TECHNOLOGY**



### **Established revenues**

Track record of revenues de-risks development and sales expansion

### **Focus on profitability**

High margin, high volume sales, with focus on production efficiencies

### **Strong portfolio growth**

Substantial product growth with 5 products expected by end of 2018

### **Geographic expansion**

Expansion underway into key US and EU markets, with multiple patents issued (expire 2031+)

### **Strong sector tail-winds**

Surging global MDx market growing from US\$6bn to US\$12bn in 2022

## **3BASE™ TECHNOLOGY REDUCES COMPLEXITY IN GENETIC TESTING ALLOWS TESTING FOR MORE DISEASES WITH HIGHER ACCURACY MORE RESULTS, MORE ACCURACY, LOWER COST**

### **3base™ technology**

- **3base™** platform technology converts original 4-base microbial genome to 3-base
  - Reducing complexity in molecular testing
- Conversion occurs during standard procedures with no additional steps for the technician

### **3base™ MDx testing is focused solely on the detection of infectious diseases**

- ✓ **3base™** MDx can identify a **wider array** of patient infections than current diagnostics
- ✓ Reduces **time to results** (5 vs 24+ hours for conventional methods)
- ✓ Provides greater testing **accuracy by reducing complexity in a single test sample**

### **3base™ technology in the detection process**

#### **Regular cell Lysis and preparation steps**

Original genome



**3base™**  
conversion

Converted **3base™**  
genome



**Standard Real-Time  
PCR instrument**

**1,048,576** combinations for a 10 digit number with 4-base

G	C	C	T	C	A	C	T	T	C
↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
G	T	T	T	T	A	T	T	T	T

**59,049** combinations for a 10 digit number with 3-base

# Powerful evidence of efficacy from clinical trials

## Clinical trials demonstrate efficacy

Evaluation study conducted at St Vincent's Hospital, Sydney

221 patient samples tested and compared to traditional culture, microscopy, and antibody based tests

Results highlight the efficacy of 3base™ technology and GSS products

- ✓ **Faster screening:** Generated results in 4 hours, compared to up to 120 hours for traditional testing methods
- ✓ **Greater accuracy:** Identified 44 infections that existing testing missed

## St Vincent's Hospital Evaluation Study results

Pathogen	Conventional Methods*	EasyScreen™
Campylobacter	7	9
Salmonella	8	9
Shigella	5	6
C. Difficile	3	7
Yersinia	-	1
Cryptosporidium	-	1
Giardia	9	12
Dientamoeba fragalis	4	20
Blastocystis hominis	16	21
Entamoeba histolytica	1	1
Norovirus group 2	-	7
Adenovirus	-	1
Adenovirus 40/41	-	1
Sapovirus	-	1
<b>Total</b>	<b>53</b>	<b>97</b>

**Significantly greater efficacy**

GSS is commercialising a range of **MDx tests** based on **3base™** and branded as **EasyScreen™**

**EasyScreen™** kits offer faster and more effective detection of infectious disease

- ✓ Four product families available covering **enteric microorganisms, respiratory viruses (including influenza), ESBL & CPO “Superbugs” and STIs**
- ✓ Target customers are high-volume hospitals and pathology laboratories

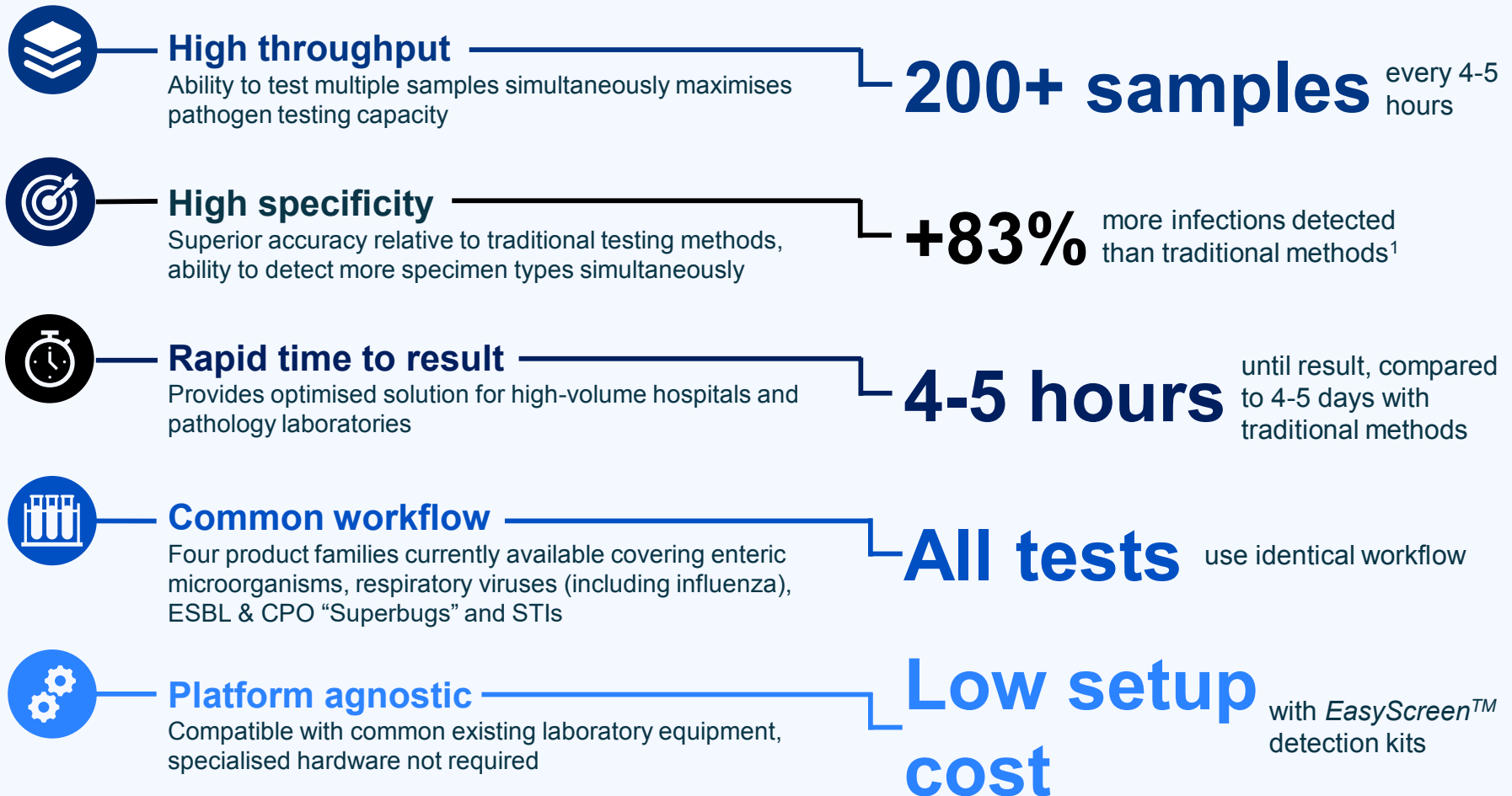


- ✓ **Common Workflow** – *all tests work under identical conditions*
- ✓ **Platform agnostic** – *compatible with common existing laboratory equipment*
- ✓ **High specificity** – *superior accuracy of results*
- ✓ **Rapid time to result (4 - 5 hours)** – *would traditionally take 4 - 5 days*

**EASYSscreen™ KITS IDENTIFY MORE PATHOGENS IN LESS TIME**

# The EasyScreen™ competitive advantage

## EASYSscreen™ KITS OFFER FASTER AND MORE EFFECTIVE DETECTION OF INFECTIOUS DISEASE; OPTIMISED FOR HIGH THROUGHPUT LABS



Notes:

1: St Vincent's Hospital Evaluation Study results, see page 6 for further details on the study



# Q4 FY18 trading update

## INTERNATIONAL EXPANSION GAINING MOMENTUM

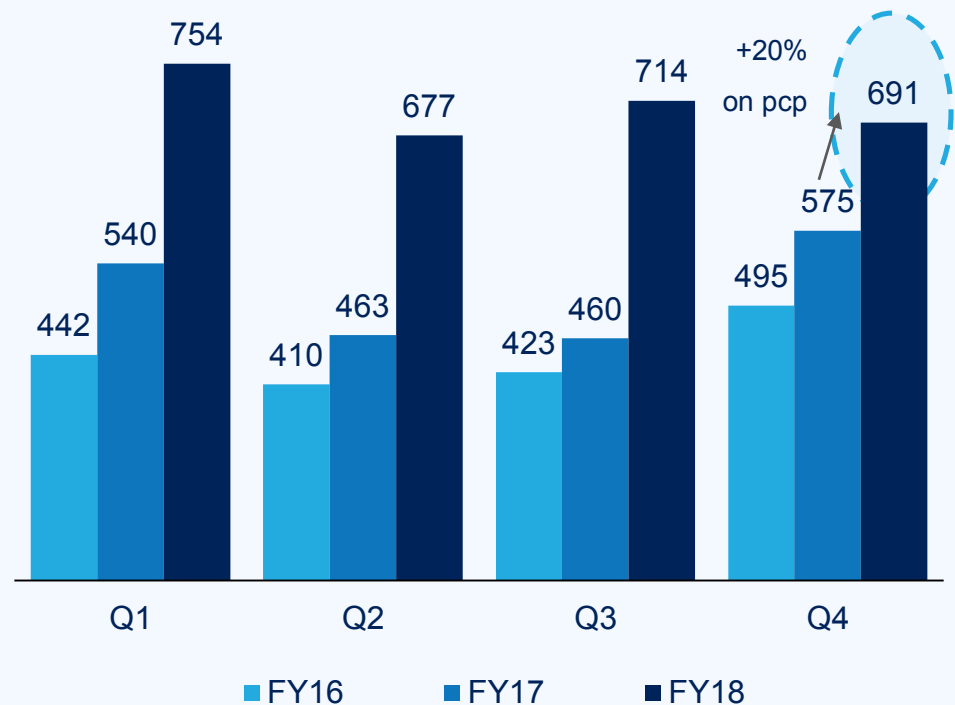
### Q4 FY18 Revenue Update

- ✓ **Strong quarterly revenue growth to A\$691k in Q4 FY18**, a +20% increase on pcp
- ✓ **First sales in the US**

Q4 performance continues **consistent quarter-on-quarter revenue growth** since listing in 2015

Strong full year revenue of A\$2.8m for FY18 representing a **+39% increase** from FY17

Quarterly revenue (A\$000)



# Key corporate and operational milestones achieved

## GSS HAS MADE STRONG PROGRESS OVER THE LAST 18 MONTHS

- ✓ Successful clinical trial results for **Flavivirus Detection Kits** at prestigious European conference in April 2017
- ✓ TGA and CE-IVD Mark approvals received for the entire **Enteric product suite** by June 2017
- ✓ Approval received for **3base™** patent in the USA until 2033
- ✓ First sale and delivery of **Flavivirus and Alphavirus Detection Kits** to an offshore customer in June quarter 2017
- ✓ Relocation to larger facilities in Sydney to accelerate next phase of operational growth
- ✓ Successful beta-release of second-generation **Respiratory Detection Kits** in September quarter 2017
- ✓ Record quarterly revenues of A\$754k in September quarter 2017 driven by strong domestic flu season
- ✓ Maiden sales for **ESBL & CPO (“superbug”) Detection Kits** for use in a trial in December quarter 2017
- ✓ Expansion of European team with appointment of field scientist and sales staff, with further recruiting continuing
- ✓ CE-IVD Mark approvals received for **ESBL & CPO Detection Kits** (‘antibiotic resistance’) in April 2018
- ✓ Successful trial results for **ESBL & CPO Detection Kits** presented at major European conference in April 2018
- ✓ Maiden sales in the USA with sales order for **ASR kits** in May 2018
- ✓ TGA registration received for **ESBL & CPO Detection Kits** in May 2018
- ✓ **Major customer contract signed** with large Australian pathology service provider in August 2018

## **GENETIC SIGNATURES HAS A CLEAR FOCUS ON REVENUE GROWTH IN FY19 DRIVEN BY ITS INTERNATIONAL EXPANSION AND NEW PRODUCT RELEASES**

### **Roll-out of expanded product suite**

- Current expectations of 5 product groups to be approved in the near term across target regions
- Continued progress with international registrations

### **Targeted international sales expansion**

- Sales expansion into North America (US\$4.6bn market) and Europe (US\$1.6bn market)
- Multiple trials underway in the US, Europe and Australia

### **Capitalise on the growing MDx opportunity**

- Independent projections of total MDx revenue reaching >US\$12bn by 2022
- Substantial current corporate activity within the MDx sector several acquisitions underway

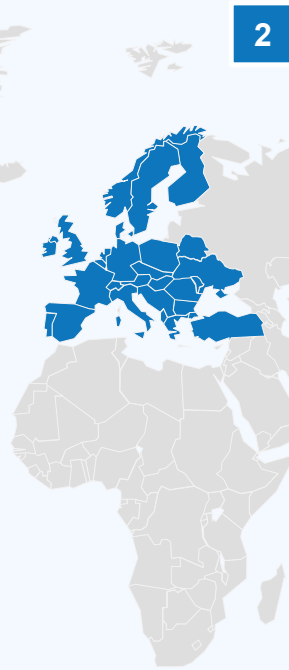
## MULTIPLE TRIALS UNDERWAY IN THE US, EUROPE AND AUSTRALIA



**3 North America: Accelerate direct sales approach**  
*Trials underway*

- ✓ First ASR sales achieved in the US
- ✓ Sales permitted through US FDA listing and ASRs
- ✓ Certified for Health Canada

*Immediate focus on securing trials with larger pathology labs*  
*ASR product trials underway*



**2 Europe: Rapidly increasing footprint to be ready for product approvals**  
*Trials underway*

- ✓ Distributors appointed (Italy, Israel, Ireland and Poland)
- ✓ CE-IVD approvals granted for enteric and ESBL & CPO
- ✓ 3 products approaching CE-IVD approval in 2018
- ✓ Appointment of a European based field scientist and other sales staff and still actively recruiting

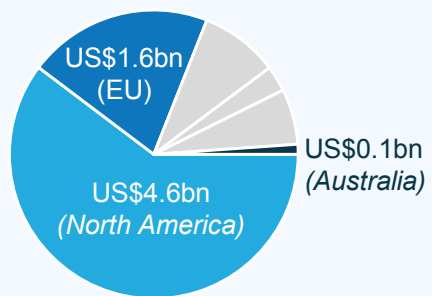
*Plan to appoint additional distributors in short term*  
*Product trials underway*



**1 Australia: Continued rapid growth**  
*Small base of customers with a number of trials underway*

- ✓ Major new contract signed for respiratory kit
- ✓ 2 products approaching TGA approval in 2018

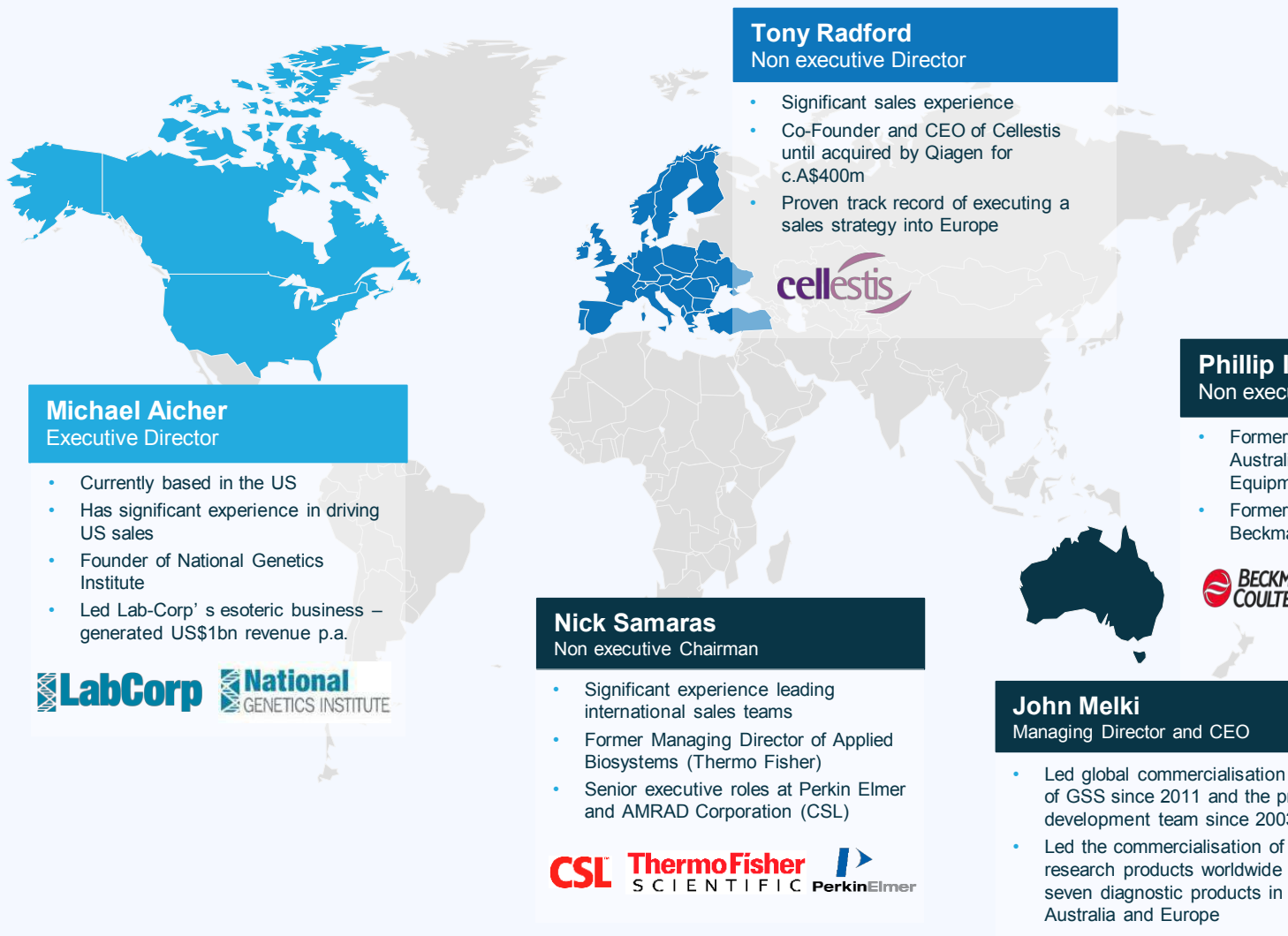
*Further customer acquisitions planned in FY19*



**Estimated MDx market size (2017)**

*Source: World Market for Molecular Diagnostics, 5th Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 94.*

# Board of Directors have a track record of success



# 1 Australia: continue rapid growth

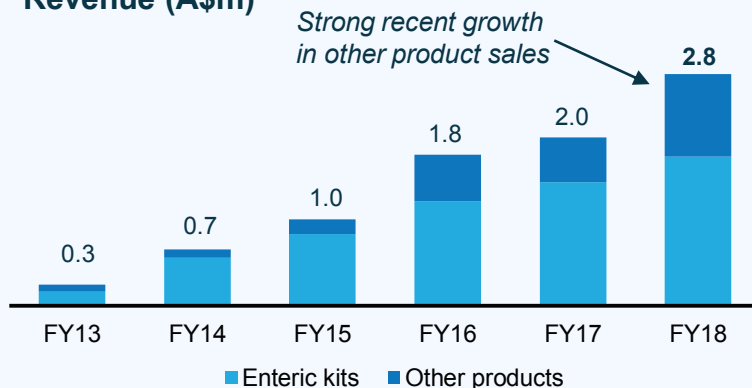
## AUSTRALIA IS THE PLATFORM FOR INTERNATIONAL SALES

### Commercialisation progress

#### Established foothold

- Secured relationships with **top tier customers in NSW and Victoria**
- **Major customer contract signed** with large Australian pathology service provider in August 2018
- Established customer relationships **increase ease of new product sales**
- Platform in NSW and Victoria has driven **strong revenue growth over last 4 years**

#### Revenue (A\$m)



Sources:

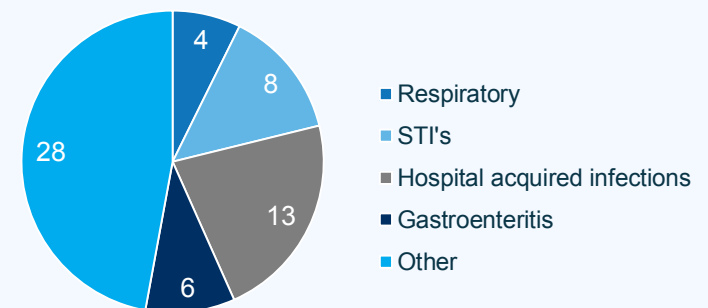
1: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 94.

### Next steps

#### Rapid customer acquisitions

- Targeting trials with large hospitals and clinical labs in Australia to provide **significant domestic revenue growth**
- 2 products approaching TGA approval in 2018 expected **drive new customer acquisitions**
- Target customers include **pathology labs, hospitals** and large **research laboratories**

#### Australia MDx market potential (US\$m)



## 2 Europe: strong progress on multiple fronts

### ACTIVELY INCREASING PROFILE IN PREPARATION FOR PRODUCT APPROVALS

#### Commercialisation progress

##### Distributors hired and evaluations underway

- Currently **adding to European team**
- **Field scientist appointed** based in Europe
- Recent **CE-IVD registration for ESBL & CPO “superbug”** Detection Kits
- **Sales logistics being finalised** with EU-based warehouse in final legal review
- Building traction with customers with **sales order received** across a number of products
- Established VAT deferment program

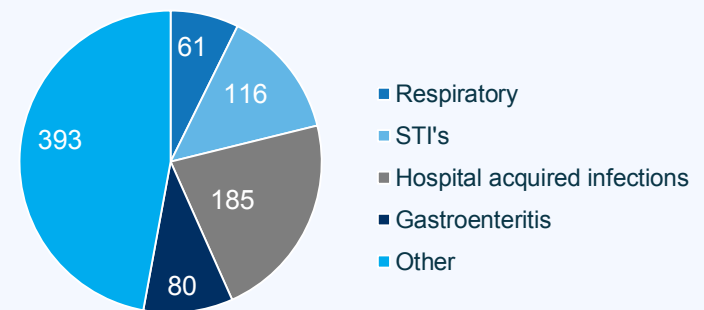
**Genetic Signatures is developing a mix of direct sales and partnerships with distributors across Europe to optimise the sales network**

#### Next steps

##### Strategic market with large opportunity

- Europe has an addressable MDx market of **c.US\$435m** - *c.20% of the global market<sup>1</sup>*
- Continue to drive revenue growth and pursue regulatory registration for STI and respiratory products in Europe
- **Actively recruiting sales and support staff** in multiple countries
- Advanced discussions with new distributors in other European countries

##### European MDx market potential (US\$m)



Sources:

1: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 94.

# 3 North America: accelerate direct sales approach

## FIRST ASR SALES AND PROGRESS TOWARD FDA CLEARANCE

### Commercialisation progress

#### Increasing traction with ASR approach

- **First ASR sales contract received** with US pathology laboratory
- Several **labs assessing the potential for ASR products** available for sale in the USA
- **Initial trials established** with local clinical labs using GSS supplied products in FY17
  - Trials reaching conclusion
- Also progressing towards **securing FDA clearance** for Enteric Protozoan Detection Kit
- **3base™** technology has patents issued in the US
- Quality Management System **certified for Health Canada**

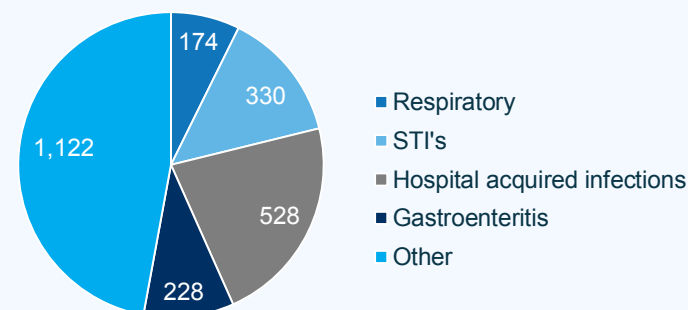


### Next steps

#### Largest market for MDx globally

- Addressable market of approximately **US\$1,265m**, c.55% of the global market
- Over 5,600 registered hospitals in the USA and 11,000 CLA certified laboratories
- FDA listings of Clinical Concentrators in place to allow initial sales

#### North American MDx potential<sup>1</sup> (US\$m)

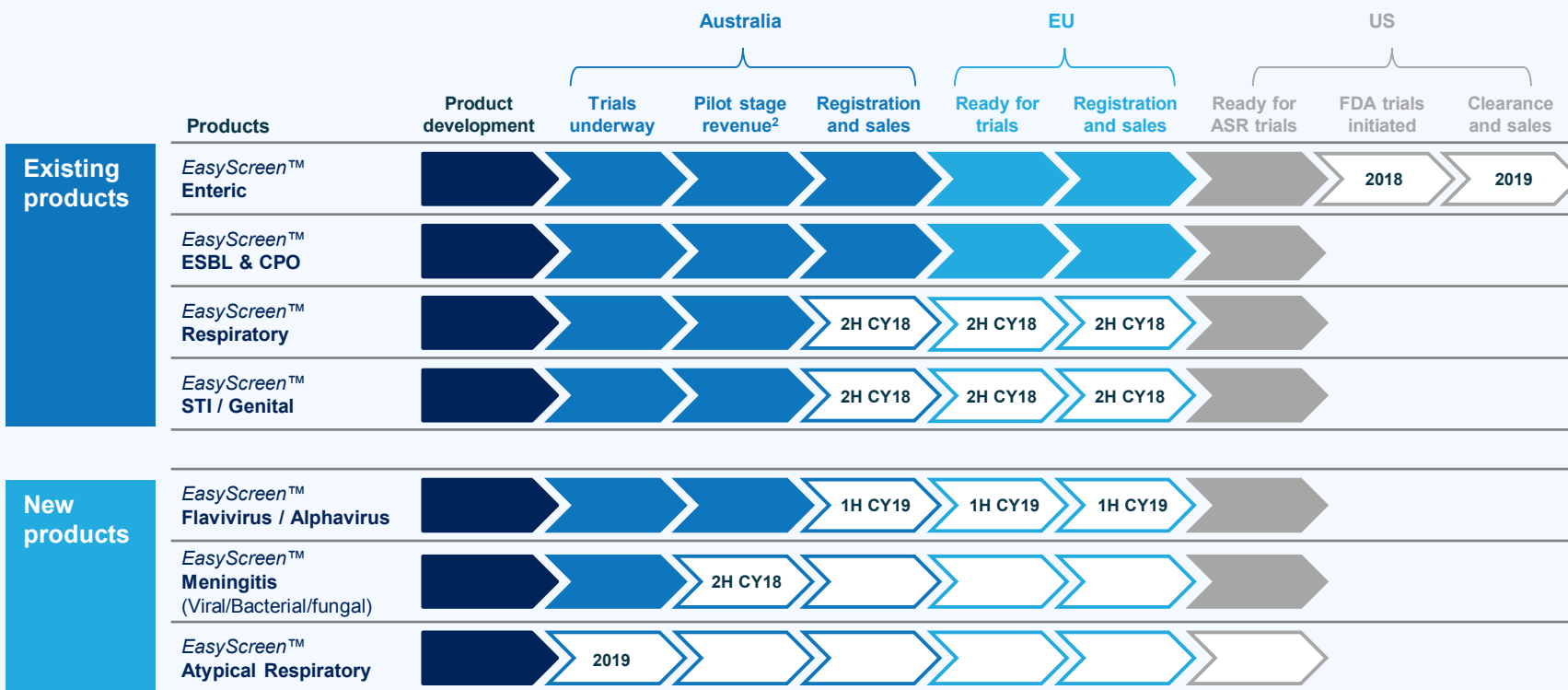


Sources:

1: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 94.



# Clear path to global commercialisation for all products

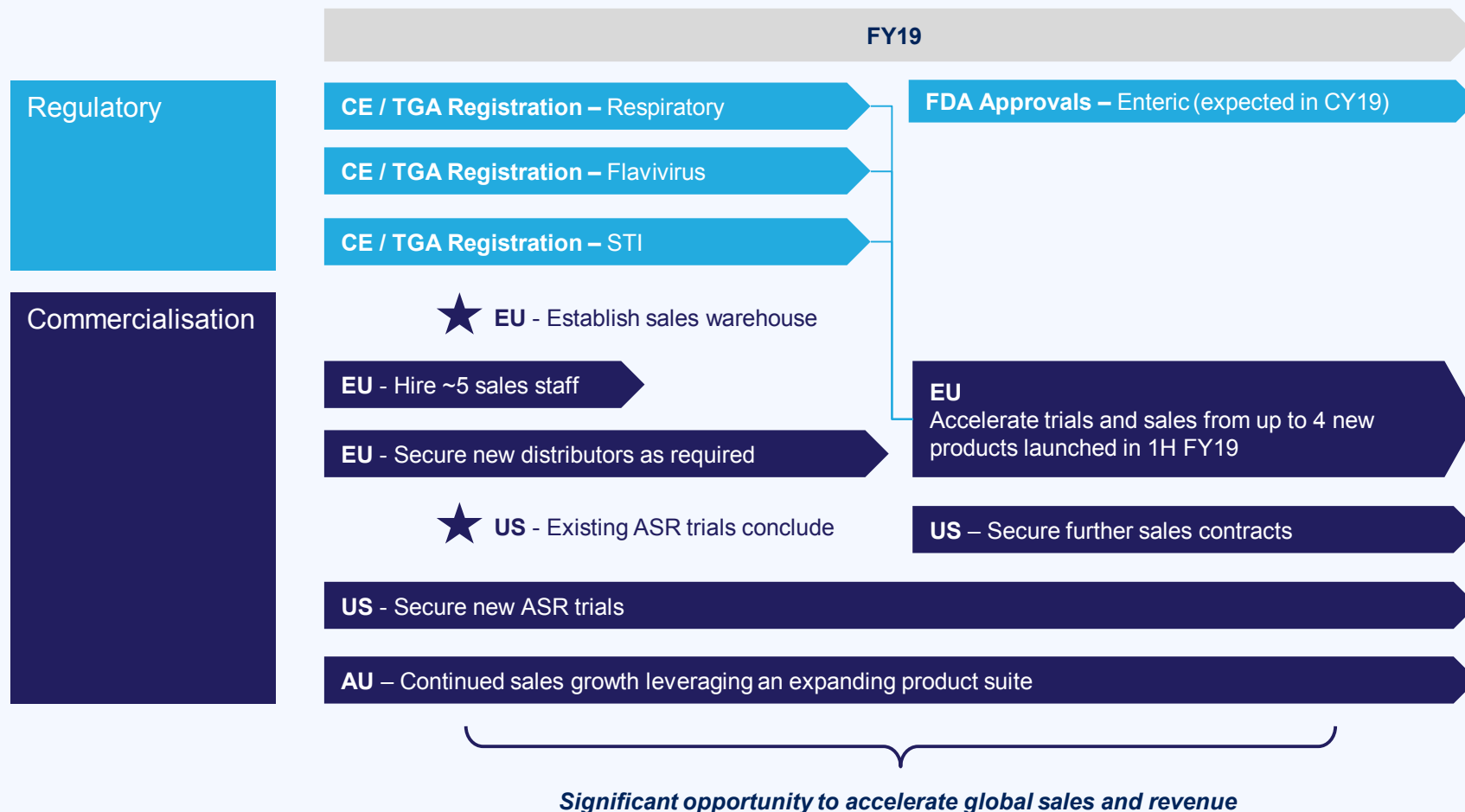


Notes:

- 1: Each of the product suites may contain multiple different individual products, requiring multiple regulatory submissions and registrations for a suite of products
- 2: Pilot stage revenue generated from sales for research use only (medical professionals may use products for diagnosis only where they validate results with independent testing)
- 3: Sold as individual Analyte Specific Reagents (ASR) for a number of pathogens in the USA

**GSS HAS MADE SUBSTANTIAL PROGRESS ON ALL PRODUCTS SINCE IPO**

## GSS IS WELL POSITIONED TO DELIVER ON ITS GLOBAL COMMERCIALISATION STRATEGY IN FY19



# US\$1.2bn market opportunity for 3 existing products



## ENTERIC

Commercialisation underway with **full regulatory registration in Europe received**

### **3base™ advantages:**

- Tests for over 20 potentially deadly enteric pathogens including *Salmonella*, *C. difficile* Bacteria and Protozoan species
- Successful trials and validation with higher accuracy, sensitivity and detection rates

### **Market opportunity:**

# US\$380m

Global addressable market  
(2017)



## RESPIRATORY

Significant growth opportunity with **registration in Australia and Europe in progress**

### **3base™ advantages:**

- Simultaneously identifies 15 of the most common respiratory infections
- Rapid screening across high volume sample sets
- Detects significantly more respiratory infections compared to existing methods

### **Market opportunity:**

# US\$290m

Global addressable market  
(2017)



## STI

Innovative STI detection kit testing pathogens **contracted by 1 million people daily**

### **3base™ advantages:**

- Proven market (sales underway)
- Highly successful clinical trials and validation
- Rapid testing for 12 pathogens
- Uses existing lab equipment
- Higher accuracy, sensitivity and detection rates compared to existing techniques

### **Market opportunity:**

# US\$550m













Global addressable market  
(2017)

Sources:

1: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 168

# Significant strategic interest in MDx technologies

- Major MDx players are pursuing aggressive acquisition strategies to secure emerging technologies
  - ...and they are prepared to pay high multiples to secure opportunities

Date ↓	Target	Acquirer	Deal value (US\$m)	EV/Revenue multiple (x)	Target Description
Mar-18	 STAT Dx Closer to Care	 QIAGEN	191	27	<ul style="list-style-type: none"> <li>• Targets enteric and respiratory infections and is focused on lower throughput</li> </ul>
Feb-18	 RHS Unique Genetic Solutions	 PerkinElmer	20	N/A	<ul style="list-style-type: none"> <li>• Provides platform for MDx processes based on single cell genomic technologies</li> </ul>
Dec-17	 ignyta®	 Roche	1,700	N/A	<ul style="list-style-type: none"> <li>• Focuses on MDx for cancer, and treatment through precision medicines</li> </ul>
Dec-16	 Multiplicom	 Agilent Technologies	72	6.5	<ul style="list-style-type: none"> <li>• Provides MDx kits for cancer, genetic disorders, pre-natal screening</li> </ul>
Nov-16	 Cepheid. A better way.	 DANAHER	3,860	5.5	<ul style="list-style-type: none"> <li>• Specializes in MDx for infectious diseases and cancer</li> </ul>
Aug-15	 GeneWEAVE	 Roche	425	N/A	<ul style="list-style-type: none"> <li>• Owns Smarticles, a type of MDx identifying multidrug-resistant organisms</li> </ul>

Source: Company filings



# APPENDIX

FURTHER INFORMATION ON 3BASE™ TECHNOLOGY

# 7 product groups underpinned by 3base™ technology

	Product group	Target pathogens	Key highlights
Four existing products groups	<i>EasyScreen</i> ™ <b>Enteric</b>	<b>20+ enteric pathogens</b> Includes Salmonella, <i>C. difficile</i> Bacteria, Protozoan and Viral Detection Kits and <i>C. difficile</i> reflex kits	All tests have full regulatory registration in Europe (10-20x the size of Aus market)
	<i>EasyScreen</i> ™ <b>ESBL &amp; CPO</b>	<b>Extended Spectrum Beta-Lactamase and Carbapenemase Producing Organisms</b>	Full regulatory registration in Europe (CE-IVD) and Australia (TGA)
	<i>EasyScreen</i> ™ <b>Respiratory</b>	<b>15 respiratory pathogens</b> (including influenza A & B, Rhinovirus and M. pneumonia)	Registrations in Australian and European markets currently in progress
	<i>EasyScreen</i> ™ <b>STI / Genital</b>	<b>12 most commonly encountered STIs</b> (including chlamydia, gonorrhoea and syphilis)	Offers superior test efficacy for pathogens contracted by 1m people daily <sup>1</sup> (market worth ~US\$550M <sup>2</sup> )
Commercial sales underway			
	<i>EasyScreen</i> ™ <b>Flavivirus / Alphavirus</b>	<b>Multiple Flavivirus/Alphavirus viral families</b> (including Zika and West Nile virus)	Offers testing for complex viruses causing widespread morbidity and mortality but historically labour-intensive to detect
	<i>EasyScreen</i> ™ <b>Meningitis (Viral and Bacterial)</b>	<b>Multiple strains of Meningitis</b> (viral and bacterial infections)	In final development stages – offers rapid diagnosis for life-threatening bacterial meningitis
Three new product groups			
	<i>EasyScreen</i> ™ <b>Respiratory Atypical Pathogen</b>	Simultaneous detection of <b>leading causes of bacterial respiratory infection</b>	In development
Trials underway			

Sources:

1: <http://www.who.int/mediacentre/factsheets/fs110/en/>

2: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 168

# Detection of infectious diseases

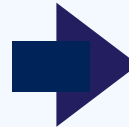
## THERE IS POTENTIAL TO TRANSFORM THE MODERN MICROBIOLOGY LABORATORY AND THE CARE OF PATIENTS WITH SUSPECTED INFECTIONS

### Current process

*Traditional methods for diagnosing infection have relied largely on identifying pathogens via culture*

#### Conventional culture-based microbiology

1. Sample collected from patient
2. Preparation of medium (i.e. agar plate)
3. Incubation
4. Analysis (i.e. microscopy)



### Industry problems

**Inefficient:** window between specimen collection and organism identification is large and can:

- × Enhance spread of infection to other patients
- × Delay onset of appropriate course of treatment

**Limited scalability:** targets often require separate tests

- × Analysis can be time consuming and require significant technician time

#### Reduced patient outcomes

- × Broad empirical antimicrobials are given to excessive numbers of patients to avoid the potential grave consequences

*Genetic Signatures' 3base™ technology can alleviate many of the pressures evident in the detection of infectious diseases and deliver improvements in time, quality and cost to meet surging demand*

# 3base™ reduces complexity by 94%

## SIGNIFICANT REDUCTION IN COMPLEXITY WHILE MAINTAINING OR INCREASING ACCURACY

**20%** improvement in homology

**94%** reduction in complexity

- ✓ Sufficient information retained for genotyping equivalent to native (4 base) genomic assays
- ✓ No loss of clinical specificity is observed by this base conversion<sup>1</sup>
- ✓ **3base™** delivers greater Sensitivity and Specificity, in a rapid assay

### 3base™ showed superior performance in HPV clinical trial

	4 base sequences	3base™ base sequences
Seq 1	GATGG <b>C</b> GAT <b>I</b> ATGGT <b>I</b> G <b>A</b> <b>C</b> <b>A</b> <b>C</b>	GATGGTGATATGGT <b>I</b> GATAT
Seq 2	GATGG <b>I</b> G <b>A</b> <b>C</b> ATGGT <b>A</b> G <b>A</b> <b>I</b> <b>A</b> <b>C</b>	GATGGTGATATGGT <b>A</b> GATAT
Seq 3	GATGG <b>I</b> G <b>A</b> <b>I</b> ATGGT <b>G</b> G <b>A</b> <b>C</b> <b>A</b> <b>C</b>	GATGGTGATATGGT <b>G</b> GATAT
Seq 4	GATGG <b>I</b> G <b>A</b> <b>I</b> ATGGT <b>A</b> G <b>A</b> <b>I</b> <b>A</b> <b>I</b>	GATGGTGATATGGT <b>A</b> GATAT
Seq 5	GATGG <b>I</b> G <b>A</b> <b>I</b> ATGGT <b>G</b> G <b>A</b> <b>C</b> <b>A</b> <b>C</b>	GATGGTGATATGGT <b>G</b> GATAT
Seq 6	GATGG <b>C</b> G <b>A</b> <b>C</b> ATGGT <b>I</b> G <b>A</b> <b>I</b> <b>A</b> <b>I</b>	GATGGTGATATGGT <b>I</b> GATAT
Seq 7	GATGG <b>I</b> G <b>A</b> <b>I</b> ATGGT <b>G</b> G <b>A</b> <b>C</b> <b>A</b> <b>C</b>	GATGGTGATATGGT <b>G</b> GATAT
Seq 8	GATGG <b>I</b> G <b>A</b> <b>C</b> ATGGT <b>A</b> G <b>A</b> <b>I</b> <b>A</b> <b>C</b>	GATGGTGATATGGT <b>A</b> GATAT
Seq 9	GATGG <b>I</b> G <b>A</b> <b>I</b> ATGGT <b>A</b> G <b>A</b> <b>I</b> <b>A</b> <b>C</b>	GATGGTGATATGGT <b>A</b> GATAT
Seq 10	GATGG <b>I</b> G <b>A</b> <b>I</b> ATGGT <b>G</b> G <b>A</b> <b>I</b> <b>A</b> <b>C</b>	GATGGTGATATGGT <b>G</b> GATAT
Consensus	GATGG <b>Y</b> G <b>A</b> <b>Y</b> ATGGT <b>Y</b> G <b>A</b> <b>Y</b> <b>A</b> <b>Y</b>	GATGGTGATATGGT <b>D</b> GATAT

75% homology over 20 bases

48 possible primer combinations



95% homology over 20 bases

3 possible primer combinations

Sources:

1: HPV clinical trial for example showed superior performance vs. Digene assay in reducing false positives (J. Clin. Virol. 42:22-6. 2008)



# EasyScreen™ customers are strong advocates

*“We use EasyScreen™ at ACL for its **robust user friendly automation, higher levels of specificity** for clinical samples and our confidence in delivering **clinically significant results** to our clinicians.*

**Tony Field**

Operations Manager

*Australian Clinical Labs*

*“Same day results and triage options for urgent requests help potentially **save lives**. And we get a high level of service and support from the GSS team!”*

*“I find that the **fast turnaround time** and the number of targets tested in the EasyScreen™ assays allow me to **more rapidly identify highly infectious agents**, potentially stopping the spread to other healthy individuals and thereby **saving the health system money**.”*

**Dr Damien Stark**

KOL and Senior Microbiologist

*St Vincent's Hospital Sydney*