Genetic Signatures

Transforming Molecular Diagnostics

510(k) Filing in Preparation for US Commercial Launch

September 2023

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Investment highlights

- **Proprietary 3base® technology platform** - a revolutionary approach to molecular diagnostic assays for infectious diseases
- **Dramatically simplifies multiple pathogen testing** from a single sample (multiplexing); more informative—simpler with fewer reagents
- **Strong commercial adoption** in AU market – expanding into EU & US
  - 4 diagnostic test kit groups cleared & commercially launched
    - 5 new kits completing development
  - Expanding network of channel partners in EMEA
  - Strong underlying growth in core revenue streams
    - FY23 sales of $16.9M with 75% from syndromic testing products
- **US commercial launch** underway with first product submitted to FDA
  - Gastrointestinal Parasite Detection kit, addresses unmet need
  - 5.5 million traditional tests conducted in the US per annum
  - Engagement started with pre-qualified customer experience sites to begin evaluating the product workflow
  - These sites are expected to become initial customers once the kit is cleared for sale

Company Snapshot

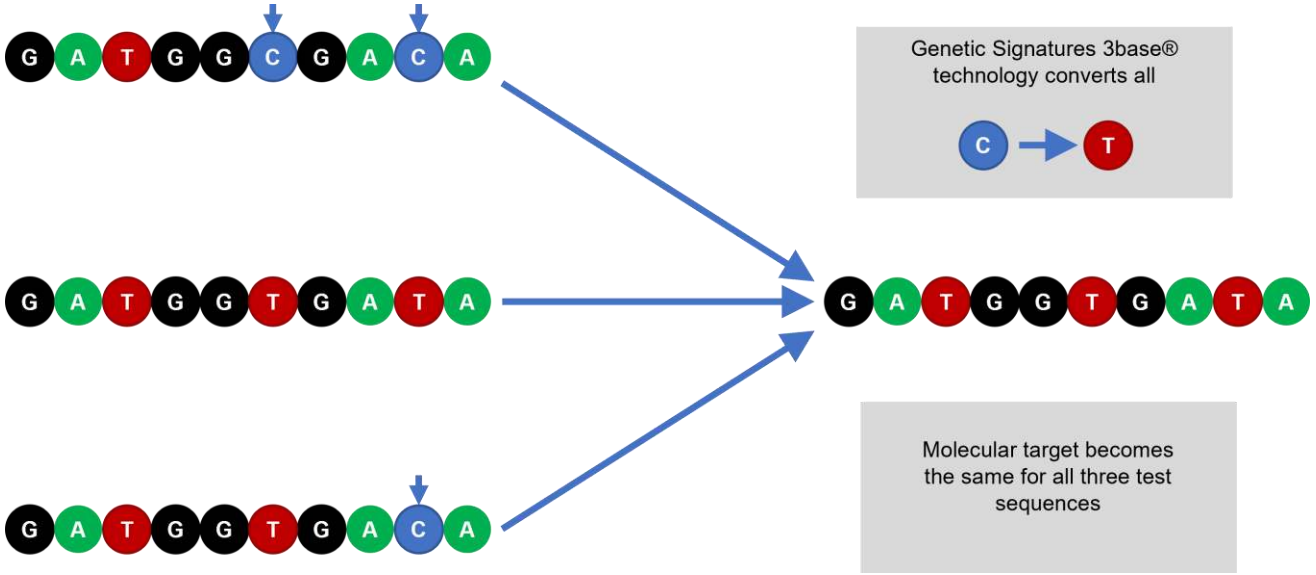
Financial information

Share price (1-September-23)	A$0.445
Shares on issue	143.4m
Market capitalisation	**A$63.8m**
Cash (30-Jun-23)	A$16.3m
Debt (30-Jun-23)	Nil
Enterprise value	**A$47.5m**

Top shareholders %

Asia Union (Chris Abbott private investment)	26.2%
Perennial Value Management	15.0%
Fidelity International	6.9%
Directors & management	3.0%

How 3base® simplifies molecular targets



* Human Papilloma virus sequences

- **Molecular diagnostic tests are based on DNA/RNA sequences**
  - DNA/RNA is unique to each organism
- **Genetic Signatures 3base®** makes multiplex testing easier:
  - **More informative** – detect related pathogens/genes using fewer tests
  - **Simpler** – fewer reagents with better matched, reaction conditions

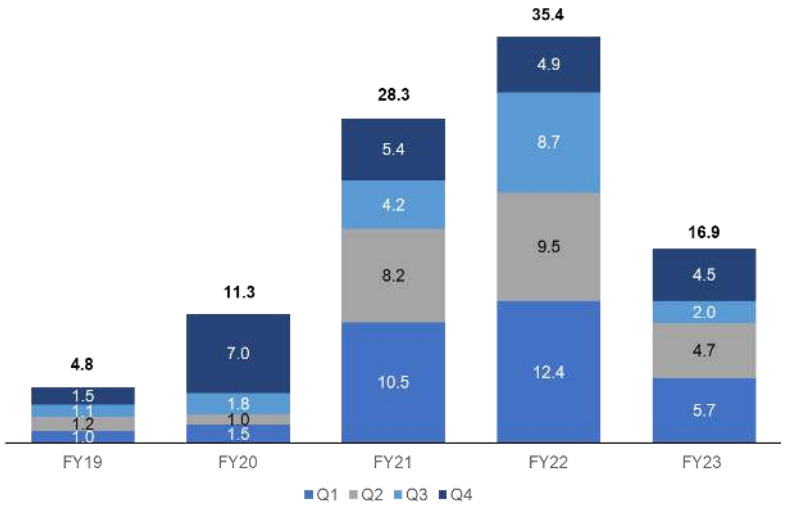
3base® conversion does not impact sensitivity or specificity and does not require any extra user steps

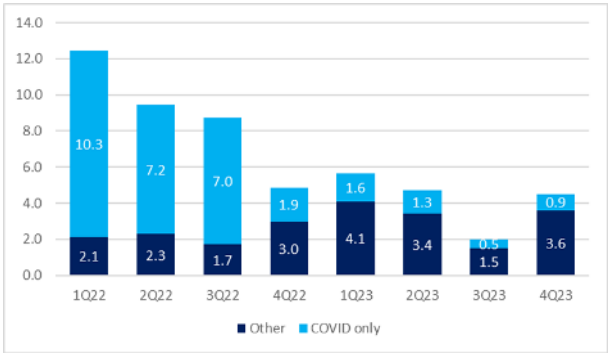
3base® simplifies syndromic testing – *EasyScreen™* Kits

- **Syndromic testing:** simultaneously test for multiple pathogens that all can cause the same signs and symptoms
  - **Respiratory infections**: cough, runny nose, sore throat, headache
  - **Gastrointestinal infections**: nausea, diarrhea, vomiting, cramps, fever
- **Syndromic testing**
  - Allows single test to determine the potential cause of a disorder
  - Avoids having to order separate tests for each possible pathogen
- **Genetic Signatures' *EasyScreen*™ is ideal for syndromic testing**
  - Tests for over 100 different types of pathogens
  - Able to detects variants (i.e. different strains or subtypes)
  - Combine tests to create *EasyScreen*™ Syndromic Detection Test Kits
  - Detect >20 different pathogens from a single sample
- **Millions of 3base® Easyscreen™ tests have been performed**

Strong underlying growth in core revenue streams

Sales Revenue (A$m)





FY23 sales $16.9 million

- Anticipated material decline in pathogen-specific molecular testing for SARS-CoV-2 experienced across the industry
- Replaced with growing syndromic respiratory sales—long-term, durable market
- Several Covid only customers currently trialing or commenced purchase of *EasyScreen™* kits for other indications
- Non-Covid only sales up 38% in FY23 and account for 75% of sales in FY23
- 9% sales to international customers—set to grow with increased EU presence and as products cleared in US

Maintain successful strategy of targeting focus towards high-volume customer groups

- High-throughput labs
- Multi-hospital groups
- Private pathology chains
- Government-led programs

FY 2023 financial results

A$'000s	FY23	FY22
Sales revenue	16,939	35,421
Cost of materials & freight	(7,996)	(11,989)
Gross profit	**8,943**	**23,432**
Employee benefits expense	(15,037)	(11,948)
Scientific consumables & clinical	(5,119)	(3,133)
Other expenses	(6,429)	(3,889)
EBITDA	**(17,642)**	**4,462**
Depreciation & amortisation	(1,526)	(1,616)
EBIT	**(19,168)**	**2,846**
Other income	5,116	217
(Loss)/profit before tax	**(14,052)**	**3,063**
Income tax	-	-
Net (loss)/income	**(14,052)**	**3,063**
Net cash inflows/(outflows)	**(20,548)**	**6,776**
Cash balance (30 June)	**16,349**	**36,897**

Reduced SARS-CoV-2 molecular testing replaced with growing syndromic respiratory sales:

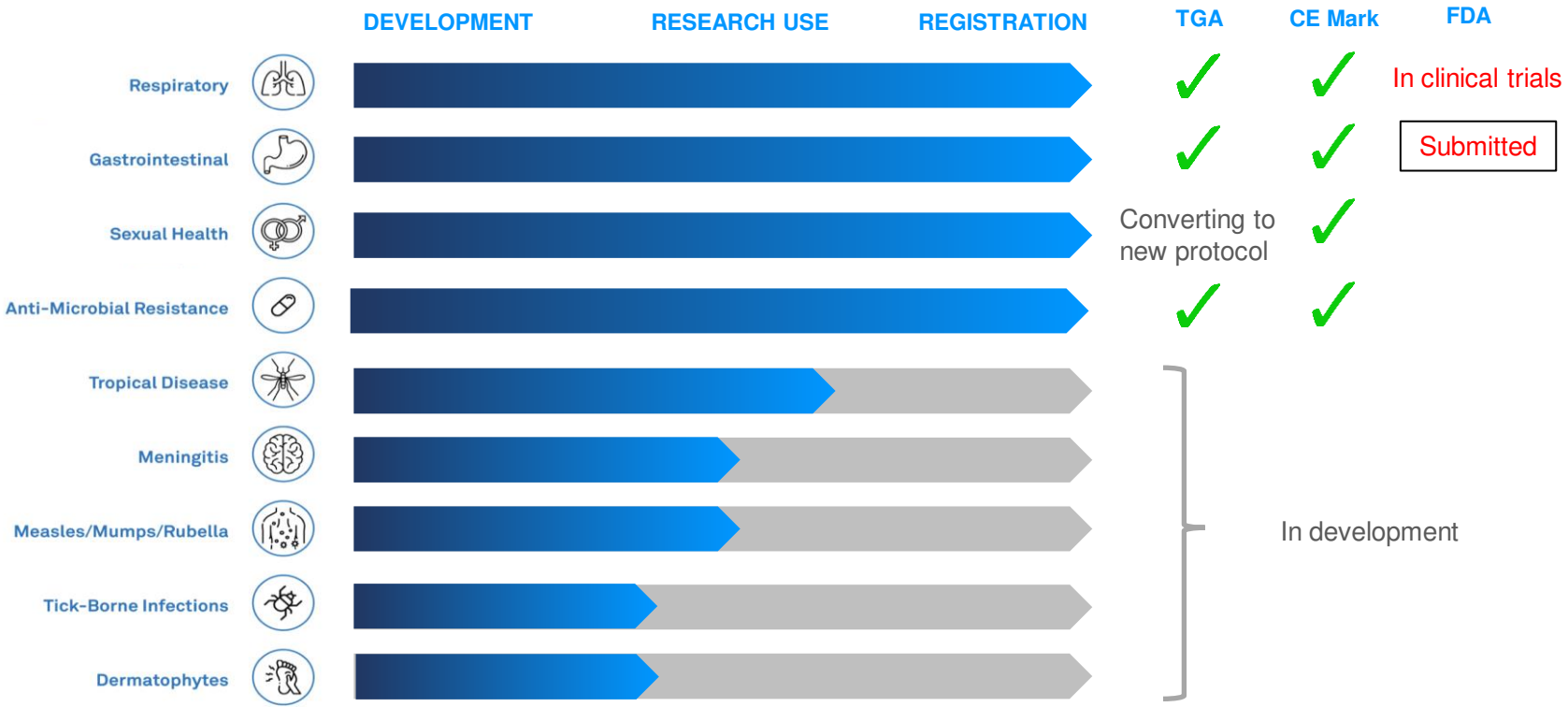
- Sales revenue of $16.9 million compared to $35.4 million in FY22;
- Non-COVID-19 only sales up 38% in FY23 and account for 75% of sales in FY23
- Gross margin on materials 60% compared to 70% p.c.p. primarily attributable to provision for obsolescence during the year
- R&D Tax Incentive receivable of $6.9m expected based on increase in eligible expenditure during the year

Substantial investments made in FY23 in growth opportunities funded from existing cash and anticipated future cash flows:

- International markets; new products; regulatory clearances; product launches; internal capabilities (clinical, regulatory); technology improvements; sample-to-result instrument.

Robust pipeline with multiple products cleared for sale

510(k) Filing
September 2023



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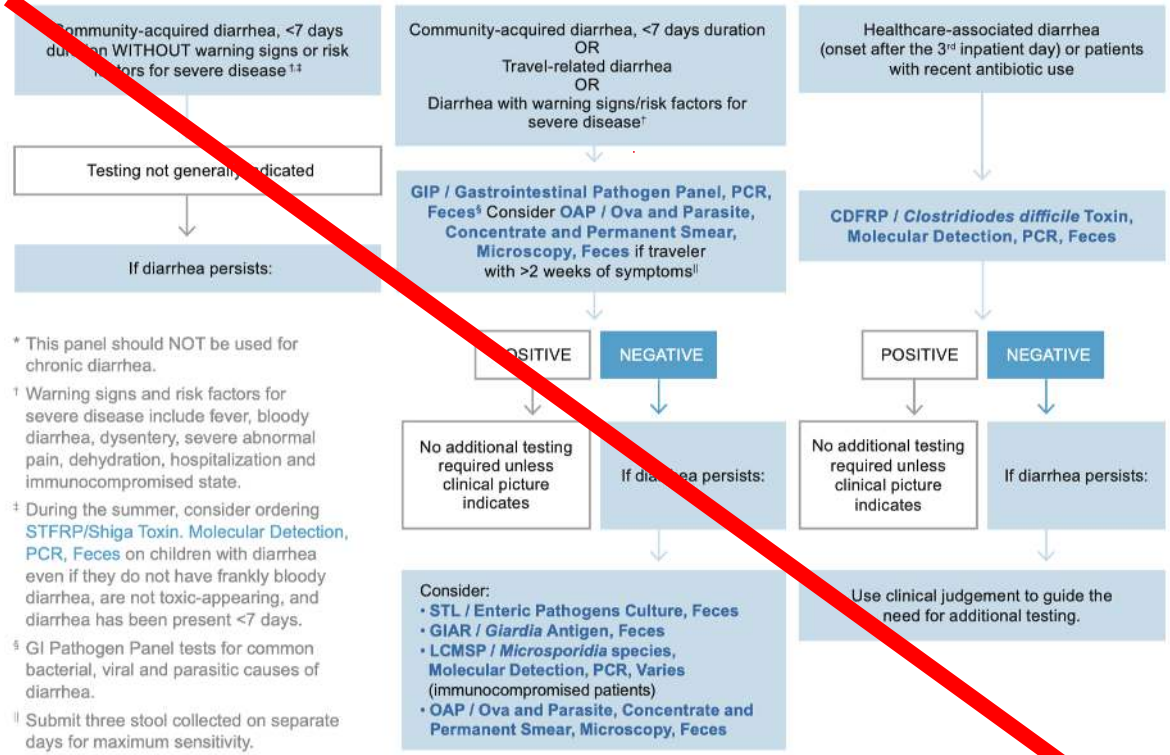
Launching into Worlds Largest Molecular Diagnostic Market

3base® supports appropriate treatment for infection

Protozoan Pathogen	Symptoms	Antibiotic
Giardia lamblia/intestinalis	Common set of symptoms from all gastric protozoan infections which include: • Abdominal pain • Diarrhea • Greasy stools • Nausea or vomiting • Gas or bloating • Dysentery • Fatigue • Weight loss	Metronizadole, tinidazole, nitazoxanide
Cryptosporidium spp.		Nitazoxanide (some patients)
Entamoeba histolytica		Metronizadole, tinidazole
Cyclospora cayetanensis		Trimethoprim-sulfmethoxazole
Enterozytozoon bieneusi		Nitaoxanide (no established guidelines)
Encephalitozoon intestinalis		Albendazole
Dientamoeba fragilis		Lodoquinol (US), secnidazole, ornidazole
Blastocystis hominis		Metronizadole, tinidazole,

- **3base®** simplifies the conditions for multiplexing several pathogen tests into a single tube
- **3base®** enables the detection of different strains and variants of pathogens within the same test

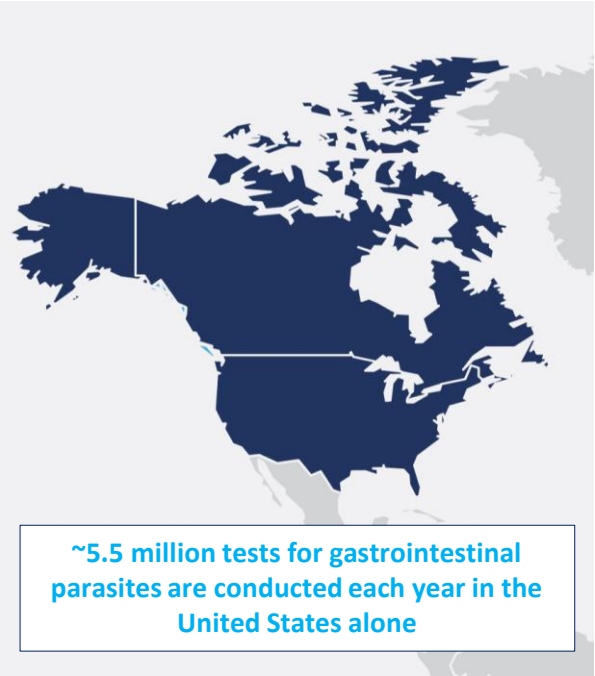
Current testing protocols are complex and inefficient



This complex inefficient process has been replaced by a streamlined molecular assay

Sourced from Mayo Foundation for Medical Education and Research

North America represents 40% of diagnostic market



~5.5 million tests for gastrointestinal parasites are conducted each year in the United States alone

- **United States has a significant commercial opportunity for testing for gastrointestinal parasites**
  - 5.5 million tests conducted in the US per annum
  - Primarily culture/microscopy: slow, labour intensive, unreliable
  - Detects leading clinically significant protozoan infections
- ***EasyScreen*™ Gastrointestinal Parasite Detection Kit fills an unmet need**
  - Syndromic, molecular solution provides a more sensitive, rapid, and broad detection for 8 leading gastrointestinal parasites
  - A number of targets are unique for GSS' solution
  - Results in hours instead of days or weeks, seen with traditional diagnostics
- **510(k) submitted with US FDA in September 2023**

Overview of molecular multiplex testing approach

Patient samples are collected which may contain more than one pathogen

Nucleic acids from both the patient and pathogens are extracted

PCR components include primers that bind specifically to pathogen target sequences of interest

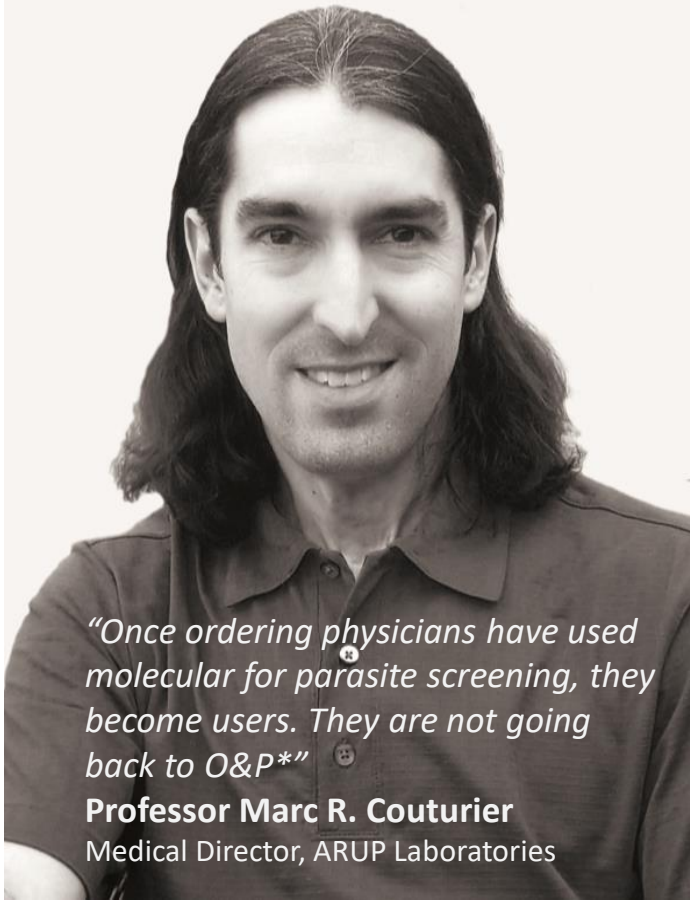
A thermocycler enables amplification of target sequences, triggering fluorescent reading

Analysis shows positive or negative results

Rapid simultaneous testing for range of pathogens that cause a similar set of symptoms in presenting patients

Significant benefits from molecular multiplex testing

- Higher sensitivity and specificity
- Able to combine multiple targets into single assay
- Workflow automation
- Quicker turnaround times



* O&P = Ova (egg) and parasite testing using culture and microscopy

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EasyScreen™ Gastrointestinal Parasite Detection Kit

Underpinned by patented **3base®** technology

Positive feedback from users in testing laboratories

"Molecular is going to impact patient management in three ways. Your results will come back quicker, they will potentially be more accurate, and they will also help ***redirect the evolving differential diagnosis by providing both positive and negative results with accuracy and efficiency."***

Dr Glen Hansen
Medical Director, Hennipin Country Medical Center *(now Chief Medical Officer at Seegene (US))*

"One of the things I really liked about the EasyScreen™ method was the range of targets that it can detect. I've seen a lot of other molecular testing that has a narrower range of targets. So ***the fact that this one has eight was wonderful to me.***"

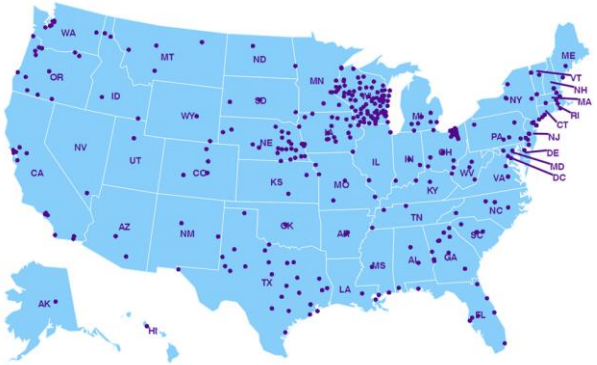
Lexi Bracken
Research Scientist, ARUP Laboratories

Since using Genetic Signatures' molecular panel for GI infections, I am able to ***rationalize and streamline our workflow. That allows for significant staff savings and cost savings.*** *The only reason we would do microscopy now is if it's a specific request for something that is not on the molecular panel"*

Principal Hospital Scientist, Australia

Preparations for commercial sales once cleared

- **Focused prospects**
  - Targeting the top 30-50 mid to high throughput laboratories in the US
  - 80/20 rule with majority of tests conducted by 20% of sites
  - Allows direct sales effort
- **Direct sales model**
  - Highly experienced sales team represented across the country
    - Actively developing customer relationships and the sales pipeline
  - Also supported by a team of technical and clinical operations experts in the region, and from HQ in Australia
- **US infrastructure established**
  - Distribution and warehouse facility in California
  - Working laboratory which houses instrumentation and enables R&D capabilities, and training support for the local market

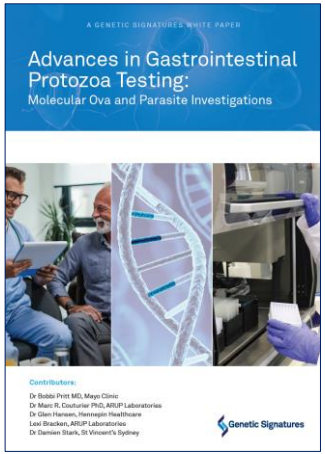


Participating laboratories in The National Respiratory and Enteric Virus Surveillance System (NREVSS). Source: CDC

Laboratory facility at BioLabs at the Lundquist Institute, California, United States

Preparations for commercial sales once cleared

US team representation at ASM Microbe 2023 conference in Houston, Texas.

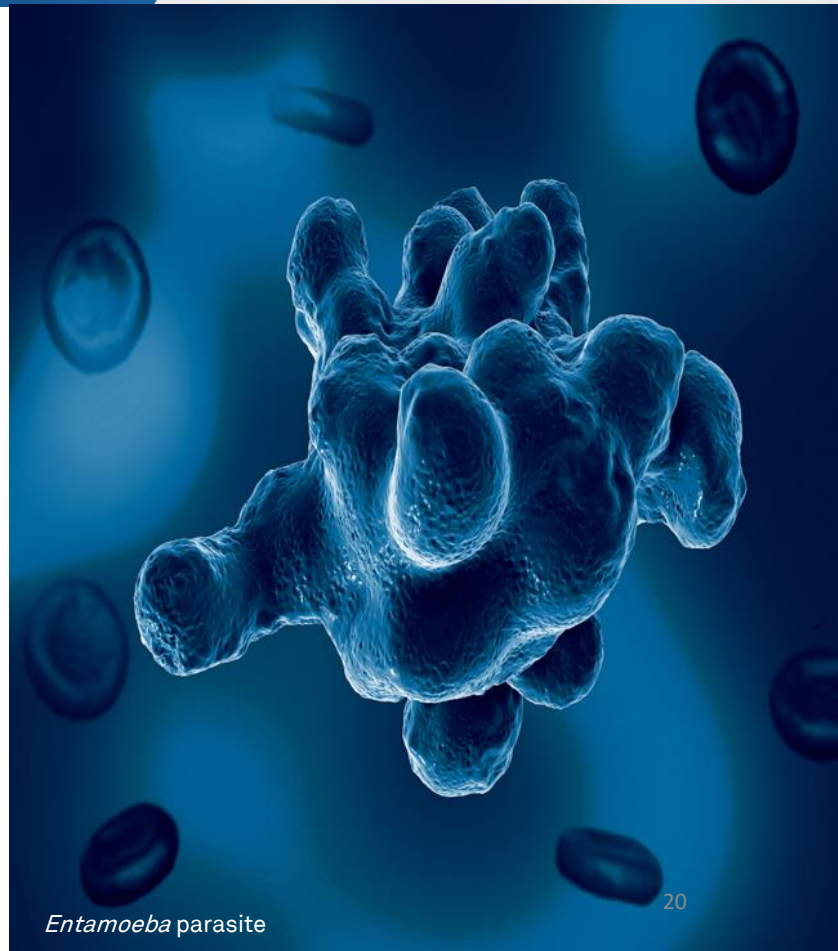


- **US market preparation activities underway**
  - Delivery of an educational webinar series and white paper involving industry parasitology experts with global reach
  - US focus group executed with key opinion leaders to deep dive into product appeal and positioning
  - Sales and marketing presence at leading international conferences in US

- **A select, limited number of pre-qualified customer experience sites in the US can now evaluate the *EasyScreen*™ Gastrointestinal Parasite Detection Kit**
  - Establish the **3base®** technology in their laboratories
  - Demonstrate the benefits of employing the **3base®** molecular syndromic testing for gastrointestinal protozoan infections

Preparations for commercial sales once cleared

- **Commercial sales expected to start soon after FDA clearance**
  - Positive forward indicators with many customer experience sites expected to transition to a purchasing customer
  - Solid opportunity pipeline supported by sales and marketing efforts in preparation of FDA clearance
  - Aiming for 40% market share of ~5.5 million tests / year
- **Product diversification for future 3base® products to follow**
  - Regulatory dossier relevant for other *EasyScreen*™ products



Entamoeba parasite

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Global Growth

Business development activity in expanding markets

- **Recent Key appointments**
  - Distributor Channel Manager – Europe
  - Regulatory Affairs and Quality Assurance Manager – Europe
  - Head of Clinical Operations – North America
- **New channel partners appointed**
  - Europe, Israel & Middle East
- **Industry meetings with solid brand exposure**
  - Europe – ECCMID and others
  - USA – ASM and others
- **Customer trials**
  - Local and international customer sites trialing other *EasyScreen*™ gastrointestinal & respiratory detection kits for adoption

Growth initiatives

- **Leverage experience in AU market to grow international sales**
  - Europe – drive adoption of other **3base®** products
  - US – build **3base®** franchise once the Gastrointestinal Parasite Detection Kit is cleared
- **Build & expand portfolio of *EasyScreen*™ products**
  - Expand menu of **3base®** tests
  - Develop new *EasyScreen*™ syndromic detection kits
  - Secure registration for new *EasyScreen*™ products
- **Embed 3base® technology in high-value customer's workflow**
  - Increase adoption of *EasyScreen*™ kits for more applications
  - Broader range of commercial arrangements with customers
- **Next Generation, "sample-to-answer" Instrument**

Prototype Next Generation Instrument

- **Next Generation, “sample-to-answer” Instrument**
  - Highly automated, little hands-on time
  - High-throughput
  - Same testing parameters for all panels – **3base®**
  - Can run multiple products in a single run
    - Highly flexible
  - Can run mixed specimen types in a single run
  - Embed use of **3base®** with customers

Images are concepts only

Upcoming milestones – 12 months

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- **US *EasyScreen*™ Gastrointestinal Parasite Detection Kit**
  - 510(k) clearance
  - Launch product once clearance is granted
- **Increase sales and presence in UK and EMEA markets**
  - Contracts with new customers
  - Direct sales force and distributor appointments
  - Expansion of BioHub laboratory in Birmingham, UK
- **Complete US clinical trial for next *EasyScreen*™ product**
  - Syndromic detection kit for common respiratory infections
  - Targeting a 510(k) submission for *EasyScreen*™ Essentials Respiratory Detection Kit
- **R&D initiatives for new products**
  - New *EasyScreen*™ detection kits
  - Technology and workflow improvements
  - Development of Next Generation Instrument prototype

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