

**MICROBA™**

**MetaPanel™**

**Australian Launch Presentation**

**ASX: MAP**  
**13 March 2024**

Authorised for release by the Board of Directors

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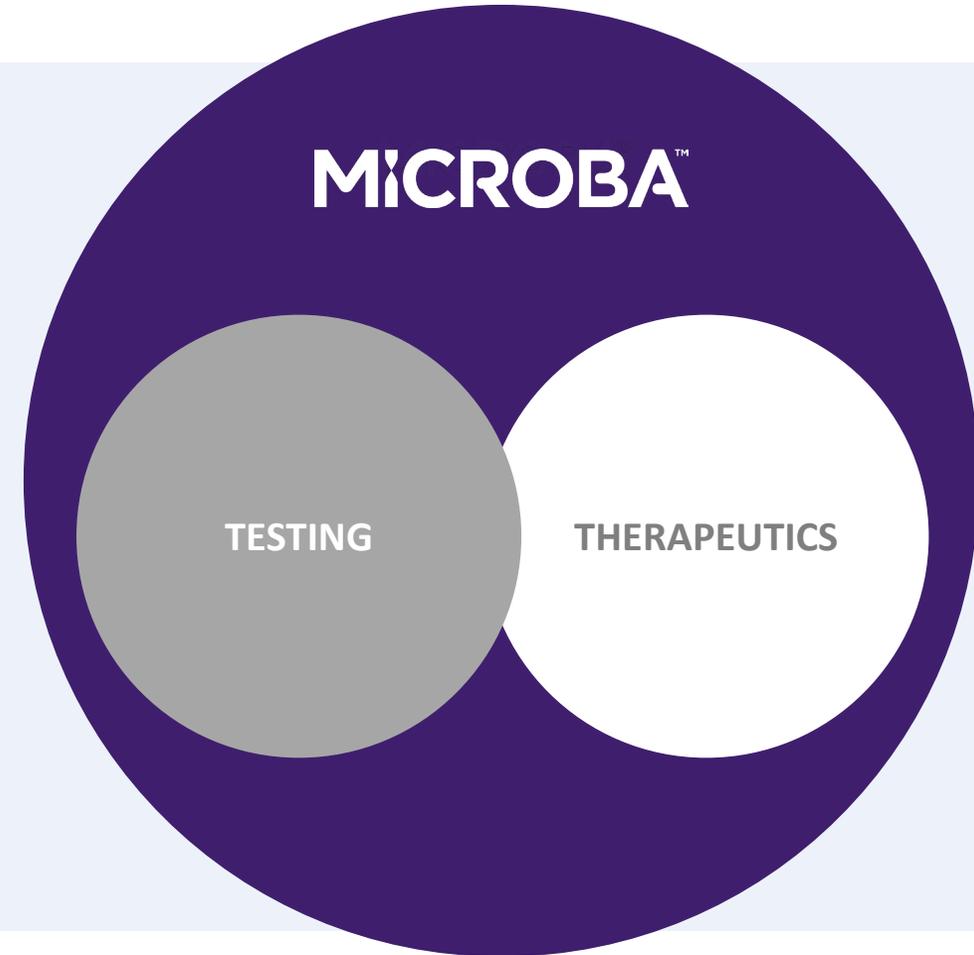
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# Microba is a Medical Diagnostic and Clinical Stage Therapeutics Company

- Microba was founded in late 2017 on world-leading metagenomic microbial genomic and microbiome analysis technology
- A clear vision for routine use of diagnostic metagenomic testing, and novel drugs developed using this technology
- Foundations and initial revenue built through *Insight* consumer microbiome test launched in 2018
- Microba's Testing business invested to develop 2 diagnostic testing products:
  - **MetaXplore™** Gastrointestinal disorder test – Launched 2023
  - **MetaPanel™** Gastrointestinal pathogen test – Launched today (2024)
- Microba's Therapeutics business invested in 3 programs:
  -  Inflammatory Bowel Disease – Phase I complete
  -  Immuno-Oncology – Preclinical lead candidate selection
  -  Autoimmune Disease – Discovery



# Microba's evolution into a medical diagnostic and clinical stage therapeutics company

	2018	2019	2020	2021	2022	2023	2024	
<p><b>Testing</b></p>	<p>Insight non-diagnostic test launched directly to consumers</p> 	<p>Agreement with Europe's largest medical diagnostics company SYNLAB. <i>[commercialisation delayed by COVID-19]</i></p> 	<p>Laboratory receives NATA ISO15189 accreditation for MetaPanel, and future diagnostics.</p> 	<p>Agreement with global medical diagnostics leader <b>Sonic Healthcare.</b></p> 	<p><b>MetaXplore™</b> launched in Australia to healthcare professionals</p> 	<p><b>MetaPanel™</b> launch (today) in Australia through Sonic Healthcare network</p> 	<p>New master agreement with Europe's largest medical diagnostics company <b>SYNLAB.</b></p> 	<p>Acquisition of UK microbiome company <b>Invivo Clinical</b></p> 
<p><b>Therapeutics</b></p>	<p>Databank starts with human research ethics approval for opt-in data collection program</p> 	<p>Therapeutic discovery commences.</p> 	<p>Allergy program with IFF Stage 1 signed</p> 	<p>AI Program established with Ginkgo Bioworks investment</p> 	<p>Allergy program with IFF Stage 2 signed</p> 	<p>AI program with Ginkgo Bioworks Stage 1 discovery complete</p> 	<p>IBD Phase 2 Ready*</p> 	



# Microba Testing Business

## Next generation gastrointestinal diagnostics

# Next generation gastrointestinal diagnostic tests

## Gastrointestinal pathogen test

### MetaPanel™



- One sample.
- 175 targets.
- Expertly curated clinical recommendations for targeted treatment.

**Clinical question:** Is it a pathogen causing these symptoms in my patient?

**MetaPanel test solution:** Detects the broadest range of pathogens, allowing for confident diagnosis or exclusion of an infectious pathogen cause for the patients symptoms

## Gastrointestinal disorder test

### MetaXplore™

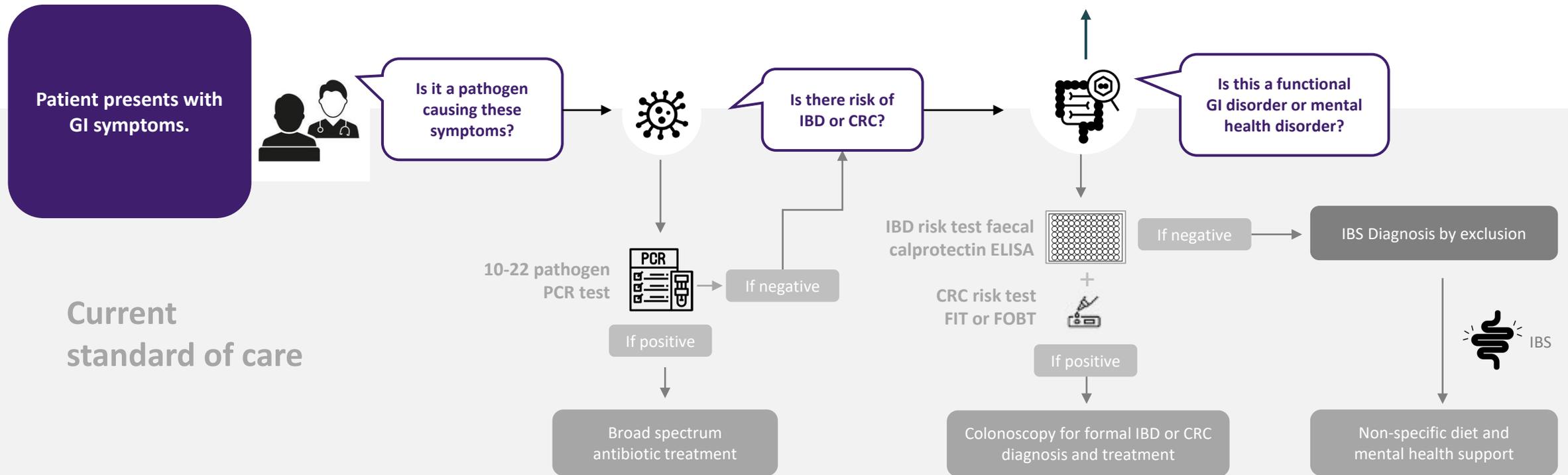


- 7 functional GI markers.
- >28k microbiome markers.
- Expertly curated clinical recommendations for personalised treatment.

**Clinical question:** Is it a functional microbiome or GI disorder causing these symptoms in my patient?

**MetaXplore test solution:** Comprehensive test covering a core set of functional gastrointestinal biomarkers, together with the most comprehensive microbiome analysis available

# Patient pathway — Advancing the standard of care for GI symptoms



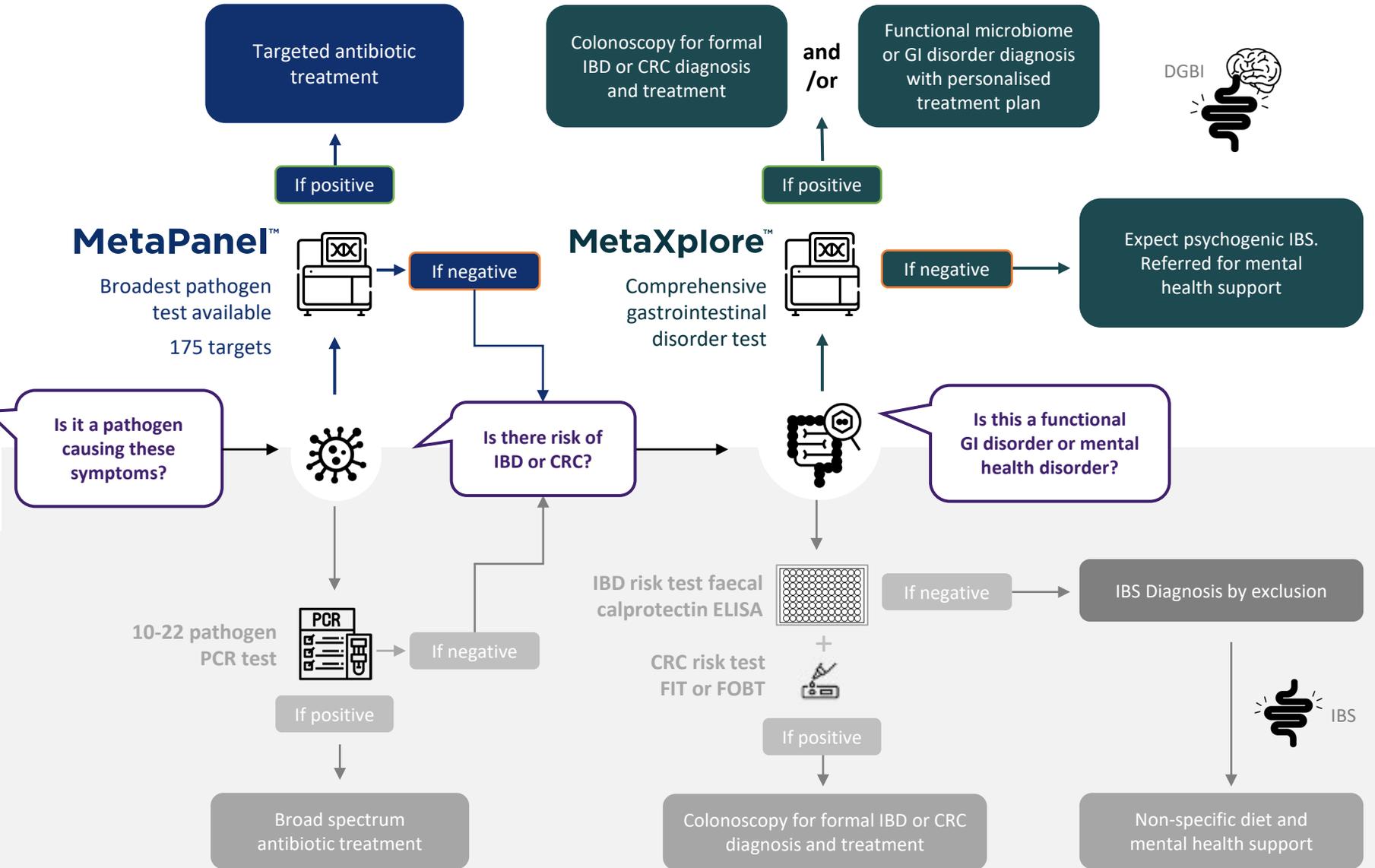
Current standard of care

# Patient pathway — Advancing the standard of care for GI symptoms

## New Microba care pathway

Patient presents with GI symptoms.

## Current standard of care



# MetaPanel

A paradigm shift in GI pathogen  
diagnosis

# MetaPanel™

## Metagenomic GI pathogen assay

A new approach for diagnosing gastrointestinal infections



**DOUGLASS HANLY MOIR PATHOLOGY** **JANE CITIZEN**  
Lab ID 987954321 | DOB 08/08/1980 144Y Female

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Goodhealth Medical Clinic  
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SUBURBTOWN NSW 2000

**005000**  
SYD/SUB

**Dr Kate Goodhealth**  
0402350367

**Referring Dr** Dr Kate Goodhealth 002 9856 3456

**Your ref.** LUCEEA6870

**Copy to** Dr John McBain  
123 Main Street  
SUBURBTOWN NSW 2000

**Requested** 09/01/2024 13:57

**Collected** 07/01/2024 08:10

**Received** 08/01/2024 11:34

**Reported** 13/01/2024 08:00

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### MetaPanel™

Metagenomic GI pathogen assay

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**Clinical history**

Chronic diarrhoea and abdominal pain, 7couse

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**Overall interpretation**

**1 Pathogen**

Acetabacter buizeri detected. This organism is closely related to Campylobacter spp. and is an uncommon cause of diarrhoea, usually acute in nature. First line treatment is with ciprofloxacin. Doxycycline is an alternative.

Cyclospora cayentensis detected. This parasite can cause both acute and chronic diarrhoeal illness and abdominal pain. First line treatment is with cotrimoxazole. Nitazoxanide is a second line alternative.

**2 Antimicrobial resistance**

Carbapenemase gene bla<sub>KPC</sub> detected.  
Risk factors for colonisation and infection include antibiotic use, prolonged healthcare exposure and recent travel to countries of high prevalence (Asia, India and the Middle East), in healthcare settings, contact precautions and use of single rooms are important measures to prevent transmission.

Fluoroquinolone resistance gene (qrnX) detected. This indicates a risk of treatment failure if ciprofloxacin is used empirically for infections caused by the Briseobacterella group but is unlikely to affect treatment for Acetabacter buizeri.

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**Overall recommendation**

Given the chronic nature of this patient's symptoms, treatment is recommended for Cyclospora cayentensis. Subsequent treatment for Acetabacter buizeri may be required in the event of ongoing symptoms.

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**References**

1. Hoge CW et al. (2016). Molecular characterization of ciprofloxacin resistance among travellers and foreign residents in Nepal. Lancet, 388(10181).

2. Van den Nieuwe AM et al. (2016). In vitro and in vivo susceptibility testing of Acetabacter buizeri and Acetabacter cyaneophilus strains isolated from Belgian patients. J Antimicrob Chemother, 71(3):1241-1248.

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Typical primary sample: Faeces

**Douglas Hanly Moir Pathology Pty Limited**  
ABN 60 003 532 895

**Results 02 9856 5918**  
Pathology 02 9856 5918 | 48 hours 02 9856 2202  
Main Laboratory 02 9856 5322 | 24 hrs 1800 222 365

**Sonic Microbiomics**

One test. 175 answers.

# Introduction to MetaPanel

- **World-first NATA accredited test** available exclusively through Sonic Healthcare across Australia
- **Comprehensive** gastrointestinal (GI) pathogen test
- **A paradigm shift in GI pathogen diagnosis** detecting both common and difficult-to-identify pathogens capable of causing infection
- **Market-leading metagenomic technology**, powered by Microba
- **Single faecal sample** easy collection at home and returned to a Sonic collection centre
- **Available now** for doctor referrals nationwide

## The MetaPanel opportunity

- Infections from a gastrointestinal pathogen are highly prevalent.
- Est. >17 million cases of gastrointestinal pathogen illness in Australia alone, every year.
- People get infected from food, water, person-to-person, and the environment.
- A standard diagnostic test can detect <20% of clinically relevant pathogens.
- Misdiagnosis or underdiagnosis has significant consequences on patient quality of life, risk of mortality, and adds significant cost to the healthcare system

**There has not been a major disruption to this diagnostic category since PCR began clinical use in the 1990s**

**~1 million stool multiplex PCR tests  
ordered in Australia to diagnose GI  
pathogens every year**

## The MetaPanel advantage for doctors and patients

- **Confidently diagnose or rule out a pathogen.** In clinical samples tested by MetaPanel\*
  - 1 in 3 identify an **additional potential pathogen** undetected by multiplex PCR
  - 1 in 3 identify an **antimicrobial resistance gene** that may add additional treatment options
- **More specific diagnosis for targeted treatment** - higher resolution than PCR resolving pathogens to species level, and identifying antimicrobial resistance genes supporting more targeted treatment
- **Clear clinical action** - Every result is reviewed by expert pathologists with personalised interpretation and treatment recommendations.
- **One single test covering all targets** – Detects >100 targets which are not currently available on any other commercial test in Australia

# The technology



# Complex data made simple for the clinician and patient

- One sample
- Processed in Microba's state of the art Next Generation DNA sequencing laboratory
- Analysed using Microba's proprietary metagenomic technology
- Test results produced by employing proprietary pathogen, virulence factor and AMR detection methods
- Report finalised by expert pathologists with personalised interpretation and treatment recommendations

Each MetaPanel sample generates  
**~7,000 books worth of genetic code data\***

MetaPanel distils that all down to  
**1 report with simple actionable results**

# Nationwide launch with Sonic Healthcare

## Starting today



## Launch events

- NSW – Douglass Hanly Moir **13<sup>th</sup> March**
- VIC – Melbourne Path. **21<sup>st</sup> March**
- SA – Clinpath Path. **26<sup>th</sup> March**
- TAS – Hobart Path. **26<sup>th</sup> March**
- TAS – Launceston Path. **27<sup>th</sup> March**
- QLD – Sullivan Nicolaides Path. **16<sup>th</sup> April**
- WA – Clinipath/Bunbury Path. **17<sup>th</sup> April**



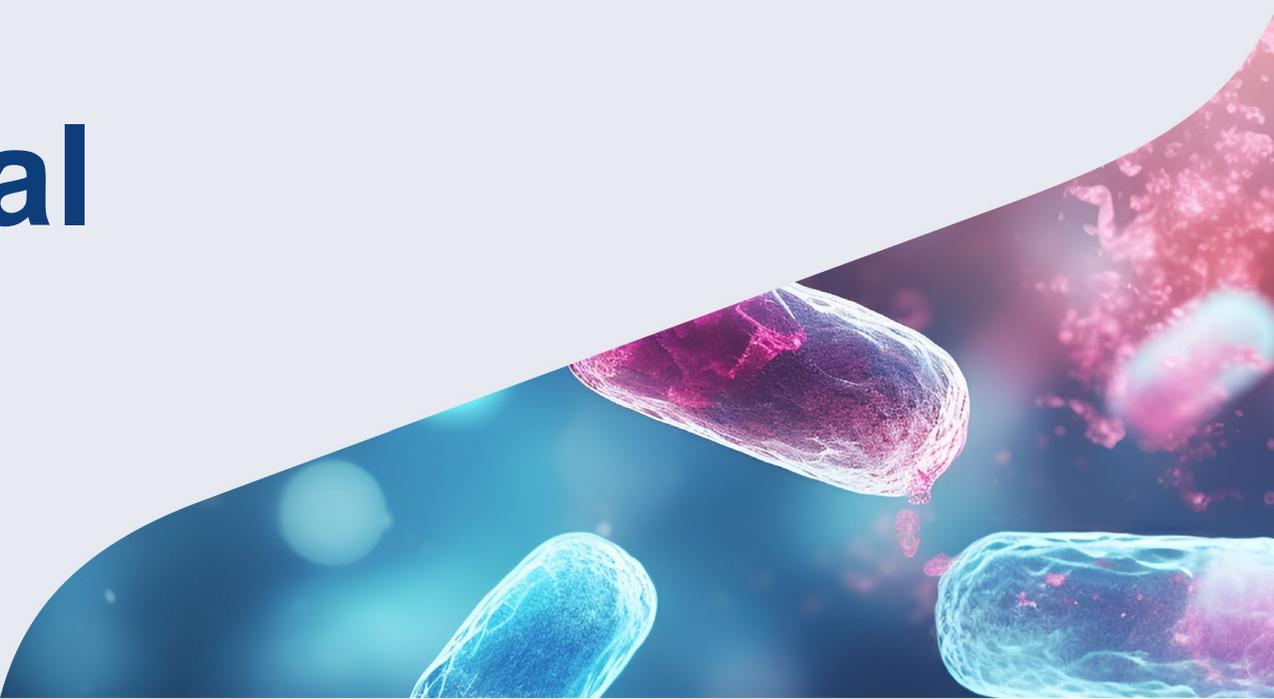
# Key Takeaways

1. **Large patient population** being underserved by current testing.
2. **MetaPanel is a step-change in technology** – no major innovation in this category since 1990s.
3. **Most comprehensive GI pathogen test available** – existing tests cover up to 22 targets, MetaPanel covers 175 targets in a single test.
4. **Proven performance** - 1 in 3 clinical samples tested by MetaPanel identify a potential pathogen undetected by multiplex PCR\*.
5. **Launching in Australia nationwide today**

# Appendix



# MetaPanel Clinical Validation



# Clinical performance validation studies

## Douglass Hanly Moir Cohort Study

- 588 patient samples
  - Age range 4m to 104
  - 160 (27%) from patients <18
- Standard of care results (micro/culture/PCR) from Douglass Hanly Moir compared with Microba's MetaPanel test result
- 837 MetaPanel tests (~150 run in triplicate)
- Consensus result defined with additional testing to resolve conflicting results

## Mater Pathology Cohort Study

- 362 patient samples
  - Age range was >18 years old
  - Subset of positive and negative samples curated from 2,619 patient specimens collected prior to test outcome after submission for identification of a causal agent of gastrointestinal infection
- Standard of care results (including MCS/OCP/PCR) from Mater Pathology Services compared with Microba's MetaPanel test result
- Consensus result defined with the inclusion of 3<sup>rd</sup> party testing to resolve discrepant results

# Strong diagnostic performance

Highly specific assay that enables confident diagnosis

Confidence Measure	Diagnostic Performance vs standard of care
<p><b>Sensitivity</b> Ability of a test to identify the presence of a target correctly; (= TP / (TP + FN))</p>	0.94 +/- 0.07
<p><b>Specificity</b> Ability of a test to identify the absence of a target correctly; (= TN / (TN + FP))</p>	1.00 +/- 0.01
<p><b>Positive Predictive Power (PPV)</b> Probability that an individual with a positive test result has the target (= TP / (TP + FP))</p>	1.00 +/- 0.01
<p><b>Negative Predictive Power (NPV)</b> Probability that an individual with a negative test result does not have the target (= TN / (TN + FN))</p>	1.00 +/- 0.01

*Data from 517 blinded samples. Confidence measures represent median values across pathogen species compared to one or more validated assays.*

# What does MetaPanel detect?



## Pathogen targets

### Bacteria



*Aeromonas caviae*\*  
*Aeromonas dhakensis*\*  
*Aeromonas hydrophila*\*  
*Aeromonas veronii*\*  
*Arcobacter butzleri*  
*Arcobacter cryaerophilus*  
*Campylobacter coli*\*  
*Campylobacter concisus*\*  
*Campylobacter fetus*  
*Campylobacter jejuni*\*  
*Campylobacter lari*\*  
*Campylobacter upsaliensis*\*  
*Chlamydia trachomatis*  
*Edwardsiella tarda*  
*Grimontia hollisae*  
*Helicobacter canadensis*  
*Helicobacter cinaedi*  
*Helicobacter fennelliae*  
*Helicobacter pullorum*

*Helicobacter pylori*  
*Listeria monocytogenes*  
*Neisseria gonorrhoeae*  
*Plesiomonas shigelloides*  
*Salmonella bongori*\*  
*Salmonella enterica*\*  
*Treponema pallidum*  
*Tropheryma whipplei*  
*Vibrio cholerae*  
*Vibrio fluvialis*  
*Vibrio furnissii*  
*Vibrio mimicus*  
*Vibrio parahaemolyticus*  
*Vibrio vulnificus*  
*Yersinia enterocolitica*  
*Yersinia frederiksenii*

### Fungi



*Candida auris*  
*Histoplasma capsulatum*

### Viruses



*Adenovirus A*  
*Adenovirus B*  
*Adenovirus C*  
*Adenovirus D*  
*Adenovirus E*  
*Adenovirus F*  
*Adenovirus G*  
*Human alphaherpes virus 1*  
*Human alphaherpesvirus 2*  
*Human betaherpesvirus 5*  
*Mastadenovirus sp.*

### Helminths



*Ancylostoma duodenale*  
*Ascaris lumbricoides*  
*Clonorchis sinensis*  
*Dibothriocephalus latus*  
*Dipylidium caninum*  
*Enterobius vermicularis*  
*Fasciola hepatica*  
*Fasciolopsis buski*  
*Hymenolepis diminuta*  
*Hymenolepis nana*  
*Necator americanus*  
*Opisthorchis felineus*  
*Opisthorchis viverrini*  
*Schistosoma japonicum*  
*Schistosoma mansoni*  
*Strongyloides stercoralis*  
*Taenia saginata*  
*Taenia solium*  
*Trichuris trichiura*

### Protozoa



*Cryptosporidium felis*  
*Cryptosporidium hominis/parvum/cuniculus/tyzzeri complex*  
*Cryptosporidium meleagridis*  
*Cryptosporidium muris*  
*Cryptosporidium ubiquitum*  
*Cryptosporidium vatorum*  
*Cyclospora cayetanensis*  
*Entamoeba histolytica*  
*Entamoeba moshkovskii*  
*Giardia intestinalis*\*

### Microsporidia



*Anncaliia algerae*  
*Encephalitozoon cuniculi*  
*Encephalitozoon hellem*  
*Encephalitozoon intestinalis*  
*Enterocytozoon bienersi*

## Virulence factors and antimicrobial resistance gene targets

### Virulence Factors

Binary toxin/CDT  
 Cholera toxin  
 Clostridium perfringens enterotoxin  
 EAEC virulence factors  
 EHEC O157:H7 virulence factors  
 EPEC virulence factors  
 Heat labile toxins  
 Heat stable toxins  
 Invasion plasmid antigen  
 Klebsiella mucoïd regulator  
 Leukocidin ED  
 Listeriolysin O  
 Shiga toxin  
 Staphylococcus enterotoxin A  
 Staphylococcus enterotoxin B  
 Staphylococcus enterotoxin C  
 Staphylococcus enterotoxin D  
 Staphylococcus enterotoxin E  
 Staphylococcus enterotoxin G

Staphylococcus enterotoxin H  
 Toxin A C. difficile  
 Toxin A&B C. difficile  
 Toxin B C. difficile  
 Yersinia stable toxin

### Antimicrobial Resistance

armA  
 blaACC  
 blaACT  
 blaAIM  
 blaCMY\_Group1  
 blaCMY\_Group2  
 blaDHA  
 blaDIM  
 blaFOX  
 blaGES  
 blaGES\_G170S  
 blaGIM  
 blaIMI  
 blaIMP  
 blaKPC  
 blaMIR  
 blaNDM  
 blaOXA-23-like  
 blaOXA-24-like  
 blaOXA-48-like

blaSHV\_E240K  
 blaSHV\_G238S  
 blaSIM  
 blaTEM\_E104K  
 blaTEM\_E240K  
 blaTEM\_G238S  
 blaTEM\_R164H  
 blaTEM\_R164S  
 blaVEB  
 blaVIM  
 CTX-M-G1  
 CTX-M-G1\_D240G  
 CTX-M-G2  
 CTX-M-G25  
 CTX-M-G8  
 CTX-M-G9  
 CTX-M-G9\_D240G  
 mcr-1  
 mcr-2  
 mcr-3

mcr-4  
 mcr-5  
 mcr-6  
 mcr-7  
 mcr-8  
 mcr-10  
 mecA  
 mecC  
 qnrA  
 qnrB  
 rmtA  
 rmtB  
 rmtC  
 rmtD  
 rmtE  
 rmtF  
 rmtG  
 vanA  
 vanB





# Microba summary

# Two core business segments driven by a world leading technology

## MiCROBA®

World leading microbiome analysis technology

Proprietary databank

Advanced AI and biostatistics powering a diagnostics and therapeutics platform

## Testing Business

Next generation gastrointestinal diagnostics

2 clinical tests.

GASTROINTESTINAL PATHOGEN TEST

**MetaPanel™**

GASTROINTESTINAL DISORDERS TEST

**MetaXplore™**

2 channels to market.

PATHOLOGY PARTNER CHANNEL



PRIMARY TARGET CLINICIANS

Gastroenterologists  
General Practitioners  
Other Specialists

DIRECT TO PRACTITIONER CHANNEL



PRIMARY TARGET CLINICIANS

Integrative General Practitioners  
Integrative Specialists  
Dieticians  
Nutritionists  
Naturopathic practitioners

## Therapeutics Business

Precision microbiome therapeutics

Data driven therapeutic development platform.

ADVANCED AI/ML APPROACH UNDERPINNED BY WORLD LEADING TECHNOLOGY

NOVEL PIPELINE OF MICROBIOME THERAPIES – POTENT, ORAL DELIVERY, SAFE & MANUFACTURABLE

3 therapeutic programs.

**INFLAMMATORY BOWEL DISEASE PROGRAM**

CLINICAL INDICATION

Mild-moderate Ulcerative Colitis

DEVELOPMENT STAGE

Phase 1 Complete  
Phase 2 Readiness



**IMMUNO-ONCOLOGY PROGRAM**

CLINICAL INDICATION

Multiple cancers to enhance check-point inhibitor treatment response

DEVELOPMENT STAGE

Pre-clinical. Lead candidate selection



**AUTOIMMUNE DISEASE PROGRAM**

CLINICAL INDICATION

Lupus, psoriatic arthritis & autoimmune liver disease

DEVELOPMENT STAGE

Discovery



# MICROBA™



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