



# Investor Presentation

• November 2024

# Forward-Looking Statement

The Private Securities Litigation Reform Act of 1995 provides a “safe harbor” for forward-looking statements. Certain information included in this presentation (as well as information included in oral statements or other written statements made or to be made by Biomerica) contains statements that are forward-looking, including statements not of historical fact; such as statements relating to - intended launch dates, sales potential, product benefits, market size, number of sufferers with IBS, prospects, new products, favorable outlook, market competition, anticipated or possible future revenues including InFoods® technology revenue opportunities, the regulatory pathway to FDA clearance, probability of FDA or other regulatory clearances, insurance reimbursement availability and amounts, physician adoption rates, efficacy and pricing of competing products, patent protection of the InFoods® technology, production volume of the Company's products, and the launch or success of current and new product offerings; as well as statements relating to the Company's products including; the efficacy of InFoods IBS at treating IBS symptoms in patients, accuracy of the InFoods product at detecting correct foods causing patient IBS symptoms, results of studies testing the Company's products' efficacy and accuracy, FDA clearance timing and requirements, EU clearance including CE Mark, the rapidity of testing results, uniqueness of these tests, use and commercial adoption of the Company's tests, pricing of the Company's test kits, domestic and international demand and orders, the Company's manufacturing capacity, patent protection, and all regulatory approvals necessary prior to commercialization of the Company's tests; and, resource and other constraints on our suppliers; dependence on our third party manufacturers; dependence on international shipping carriers; governmental import/export regulations; competition from other similar products and from competitors that have significantly more financial and other resources available; and any other aspect of the Company's tests and products. Such forward-looking information involves important risks and uncertainties that could significantly affect anticipated results in the future, and accordingly, such results may differ materially from those expressed in any forward-looking statements made by or on behalf of Biomerica. Forward looking statements also include the assumptions underlying or relating to such statements. The underlying assumptions could prove to be inaccurate or known or unknown risks or uncertainties could materialize, therefore actual results could vary materially. The potential risks and uncertainties include, among others, fluctuations in the Company's operating results, downturns in international and or national economies, the Company's ability to raise additional capital as needed, the competitive environment in which the Company will be competing, and the Company's dependence on strategic relationships and on regulatory approvals. A further list and description of these risks, uncertainties and other factors can be found in our report on Form 10-K filed with the Securities and Exchange Commission on August 29, 2022. Any forward-looking statements made in this presentation speak only as of the date of the presentation. The Company is under no obligation to update any forward-looking statements after the date of this presentation.

# Who We Are

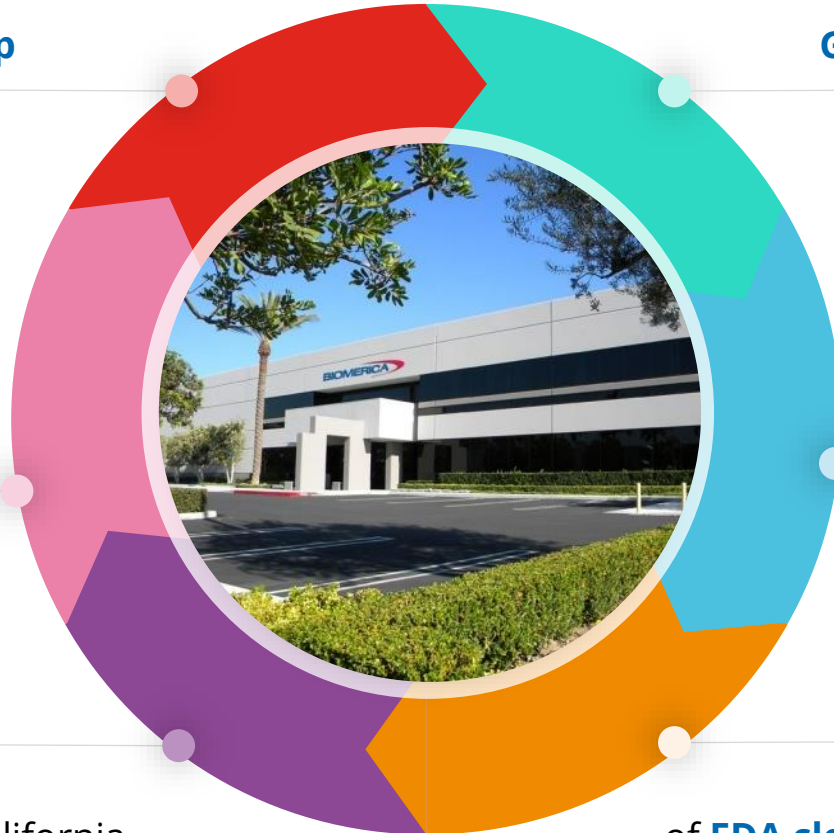
## Depth of Scientific Leadership

US Members of the Rome Foundation Clinical studies lead by principal investigators who set GI "treatment guidelines"

## Large-scale Device Manufacture

Production of products in GI and areas at 2 facilities

**2 FDA, CE, CFDA registered manufacturing facilities** in California and Mexico Headquarter: Irvine, CA, USA



## Global Biomedical Company

Develops, patents, manufactures & markets advanced diagnostics for use in Clinical lab, Point-of-Care, At-Home

## Contract Manufacturer

For 2 multinational pharma companies, Bio-Rad & other leading organization

**Experienced Manufacturer of FDA cleared & CE marked products**

## Our customers in USA



# Leadership, Board & Depth in Science

## Management



### ZACK IRANI-COHEN

- Chief Executive Officer & Chairman
- Previous CEO & Chairman of Lancer Orthodontics Inc.



### ALLEN BARBIERI

- Executive Vice Chairman
- Previous CEO of numerous public and private companies

## Independent BOD Members

**Cathy Coste, CPA**  
Former Deloitte Partner

**Jane Emerson, MD, PhD**  
Chief of Clinical Pathology, USC

**David Moatzedi**  
CEO Evolus (NASDAQ: EOLS)

## Scientific Advisory Board



### DOUGLAS DROSSMAN, MD

- President Emeritus, Rome Foundation
- Co-Director Emeritus, UNC Center for Functional GI and Motility Disorders



### LIN CHANG, MD

- Professor of Medicine, UCLA, Division of Digestive Diseases
- Rome Board member
- Served on FDA GI advisory panel



### WILLIAM CHEY, MD, AGAF, FACP, FASCP

- Professor GI & Nutrition Sciences, Univ. of Michigan
- Rome Board member
- Co-Director Michigan Bowel Program



### BRIAN LACY, MD, PHD

- Mayo Clinic
- Co-Author of ACG Guidelines



### ANTHONY LEMBO, MD

- Harvard Medical & Beth Israel Deaconess Medical Center
- Associate Editor of Journal of Clinical Gastroenterology and Digestive Diseases and Science

## Principal Investigators or Collaborators for:



## InFoods® Principal Investigators

### WILLIAM CHEY, MD, AGAF, FACP, FASCP

- University of Michigan – Ann Arbor
- Director of the Digestive Diseases Center
- Co-Author of ACG Guidelines

### ANTHONY LEMBO, MD

- Harvard – Beth Israel Deaconess Medical Center

### TISHA LUNSFORD, MD

- Mayo Clinic
- Director of the Motility Interest Group

### BRIAN LACY, MD, PHD

- Mayo Clinic
- Current co-Editor in Chief of the American Journal of Gastroenterology
- Co-Author of ACG Guidelines

### EAMONN QUIGLEY, MD

- Chief, Division of Gastroenterology and Hepatology at Houston Methodist

### BROOKS CASH, MD, AGAF, FACP, FASGE

- Chief of Gastroenterology, University of Texas Health Science Center at Houston



# Background & Innovation

Leveraging diagnostic expertise to transition into diagnostic-guided therapeutics

## **Specialty diagnostics** *enabling early disease detection and monitoring*

- Two FDA, CE, CFDA registered manufacturing facilities in California and Mexico
- Commercially launched FDA cleared diagnostic tests



## **Disruptive patented technology platform** *enabling diagnostic therapies*

- Redefining the treatment of GI diseases
- Also applicable for treating non-GI chronic inflammatory diseases
- Gross margin opportunities similar to drugs



# InFoods® – Diagnostic Guided Therapy (DGT) Personalize Medicine for IBS patients



- ➔ FDA-regulated diagnostic to be used as therapy
- ➔ Measures immunoreactivity for a panel of foods to determine which foods are above normal range and problematic for a specific patient
- ➔ Allows physicians to identify patient-specific foods which, when removed from diet, may alleviate or improve the patient's gastrointestinal symptoms and suffering
- ➔ Clinical trial guided by U.S. members of the Rome Foundation, the leading organization that sets IBS treatment guidelines

Note: Clinical lab product in clinical studies.



## Example of Patient-Specific Results

### LAB RESULTS




<b>PATIENT NAME:</b> TESTLAST, TESTFIRST	<b>ORDER ID #:</b> IBSTEST01	<b>PROVIDER NAME:</b> Self Refer
<b>DOB:</b> 01-01-1960 AGE: 63 GENDER: F	<b>ACCESSION:</b> V2211100027	<b>CLINIC NAME:</b> Biomerica Inc
<b>SPECIMEN TYPE:</b> Vial - Red Top	<b>RECEIVED DATE:</b> 01/27/2023	<b>CLINIC ADDRESS:</b> 17571 Von Karman Ave
<b>COLLECTED DATE:</b> 01/26/2023	<b>REPORT DATE:</b> 11/10/2022	<b>PHONE:</b> 949-379-2874


#### About this test

The patented inFoods® IBS test panel is designed to identify foods that cause an elevated immune response (foods with an elevated IgG level) in patients with irritable bowel syndrome (IBS). In a clinical study, patients who removed positive foods from their diet experienced reduced symptoms of IBS including pain and bloating, as well as an improvement in overall feelings of wellbeing. Discuss the results of this test and any treatment plans with your healthcare provider.

#### 1 What your results mean:



**POSITIVE FOODS:** When compared to patients without IBS, your immune response (IgG immunoreactivity) is **ELEVATED** above a normal level for this food.



**NEGATIVE FOODS:** When compared to patients without IBS, your immune response (IgG immunoreactivity) is at a **NORMAL** level for this food.

#### POSITIVE FOODS



**Rye**  
ELEVATED IgG LEVEL



**Cow's milk**  
ELEVATED IgG LEVEL



**Cocoa**  
ELEVATED IgG LEVEL



**Orange**  
ELEVATED IgG LEVEL

#### NEGATIVE FOODS



**Corn**  
NORMAL IgG LEVEL



**Oat**  
NORMAL IgG LEVEL



**Wheat**  
NORMAL IgG LEVEL



**Whole Egg**  
NORMAL IgG LEVEL



**Pineapple**  
NORMAL IgG LEVEL

# Irritable Bowel Syndrome (IBS) is Very Common and Costly

IBS is the **#1 most common diagnosis** made by gastroenterologists<sup>1</sup>

IBS is the **#7** most common diagnosis made by **all physicians**<sup>1</sup>

IBS patients visit doctors **3x more** than non-IBS patients

IBS sufferers have **74% more** direct healthcare costs vs. non-IBS sufferers

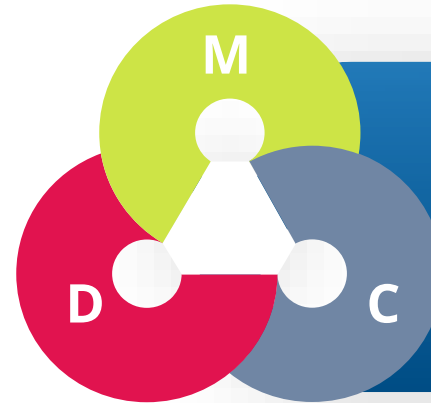
The Majority of IBS patients believe **foods trigger** their **symptoms**

<sup>1</sup>Recent AGA Survey (American Gastroenterological Association).

# IBS Market is Significant Today and Growing

## \$30B+

U.S. TAM<sup>1</sup>



# 40 Million

IBS Patients in the US

1/3 IBS-C  
(Constipation)

1/3 IBS-D  
(Diarrhea)

1/3 IBS-M (Mixed:  
Alternates C+D)

IBS = recurrent abdominal pain & change in bowel habits

**~16**  
MILLION  
**US IBS Patients:**  
seeking consistent  
physician treatment

**~13**  
MILLION  
**IBS-M Patients:**  
No approved  
therapy/drug<sup>2</sup>

<sup>1</sup>Global prevalence of and risk factors for irritable bowel syndrome: a meta-analysis. *Clinical gastroenterology and hepatology*. 2012 Jul 1;10(7):712-21.

<sup>2</sup>Irritable bowel syndrome in the United States: prevalence, symptom patterns and impact. *Alimentary pharmacology & therapeutics*. 2005 Jun;21(11):1365-75.

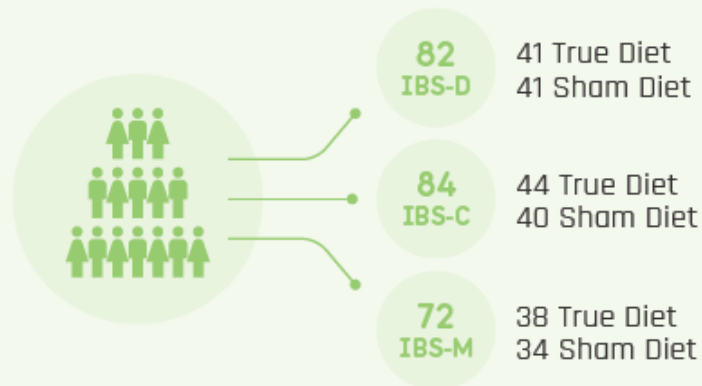


# Clinical Study

## Clinical Study of InFoods IBS<sup>1</sup>

- **Study Sites:** Mayo Clinic, Harvard Beth-Israel, Univ. Michigan, Univ. Texas Houston
- **Study Design:** 8-week, prospective, double-blinded, placebo-controlled, randomized, multi-center
- **Treatment Arm:** True Diet - Elimination of positive foods (above normal levels of IgG) from the diet of IBS patients
- **Placebo Arm:** Sham Diet - Elimination of non-positive foods from the diet of IBS patients

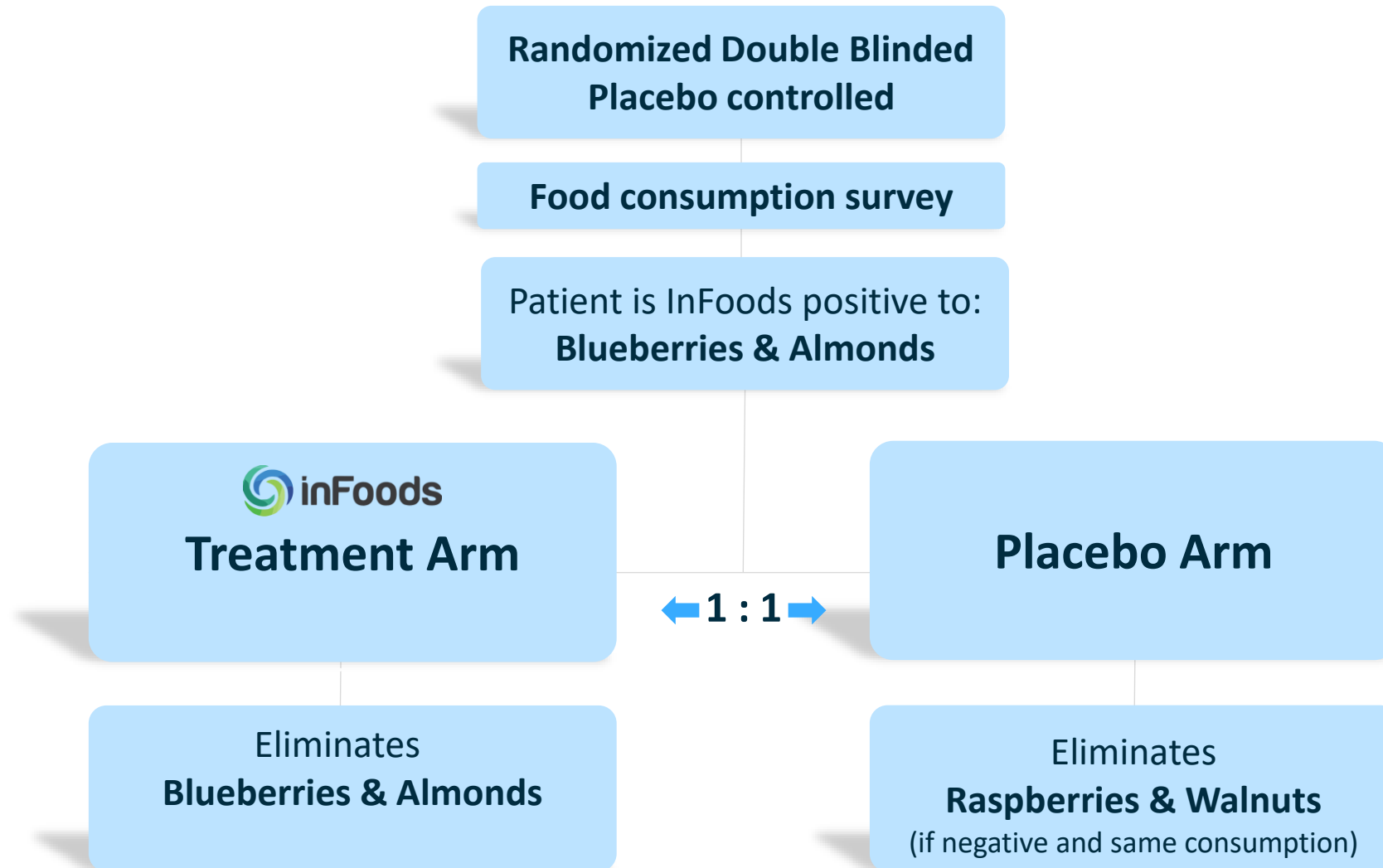
238 IBS Patients  
were randomized  
into the trial



- Mean Age: **41**
- **21.5%** Male
- **78.5%** Female
- **93.4** mean number of months treated for IBS prior to enrollment

<sup>1</sup>Endpoint Determination Study for An Antibody Guided Dietary Restriction Trial Using Biomerica InFoods<sup>®</sup> IBS Test in Patients With a Previous Diagnosis of Irritable Bowel Syndrome (IBS) ([NCT03459482](https://clinicaltrials.gov/ct2/show/study/NCT03459482))

# InFoods® IBS: Clinical Trial Design Summary



# Highlights

Statistically meaningful improvements were seen in multiple endpoints (symptoms), this is only a selection of topline results from the InFoods® IBS endpoint trial

## Global Endpoints

SGA →

GIS →

# InFoods® IBS

## Top Line - Global Endpoints

 **Treatment Arm**

**Vs.**

**Placebo Arm**

**P-value of 0.007** for improvement in the **Subject's Global Assessment of Relief (SGA)** endpoint for all patient subtypes as a group (baseline vs 8 weeks)

Subject's global assessment (SGA) of relief is a single measure (endpoint) encompassing abdominal pain/discomfort, altered bowel function, and overall well-being. This measure, which has been validated in populations with IBS, was considered the standard assessment of symptoms for IBS trials in the past<sup>1</sup>

**P-value of 0.040** for improvement in the **Global Improvement Scale (GIS)** endpoint for all patient subtypes as a group (baseline vs 8 weeks)

Global Improvement Scale (GIS) assesses multiple irritable bowel syndrome (IBS) symptoms using a patient-defined 7-point Likert scale ranging from symptoms substantially worse to substantially improved

1. Aliment Pharmacol Ther 2001;15:1655-66 & Gastroenterology 2000;118:A145

# Highlights

Statistically meaningful improvements were seen in multiple endpoints (symptoms), this is only a selection of topline results from the InFoods® IBS endpoint trial

## Pain and Bloating

API →

Bloating →

# InFoods® IBS

## Top Line - Global Endpoints

  
Treatment Arm

Vs.

Placebo Arm

**P-value of 0.012** for improvement in the **Abdominal Pain Intensity (API)** endpoint for IBS-Mixed & IBS-Constipation patients as a group (baseline vs 8 weeks)

IBS is partly defined by pain, and pain is the cornerstone of the IBS illness experience for many patients. Abdominal Pain Index (API) is the only instrument that can be scored as a composite measure of overall abdominal pain severity composed of pain frequency, intensity, and duration<sup>1</sup>

**P-value of 0.022** for improvement in the **Bloating** endpoint for IBS-Mixed & IBS-Constipation patients as a group (baseline vs 8 weeks)

Bloating is reported by up to 96% of patients with irritable bowel syndrome (IBS), is more common in females, and is often ranked as their most bothersome symptom<sup>2</sup>

1. J Pediatr Psychol. 2015 Jun; 40(5): 517-525 & Aliment Pharmacol Ther. 2010 Nov; 32(9): 1192-1202.  
2. Gastroenterology Volume 131, Issue 4, P1003-1010, October 2006

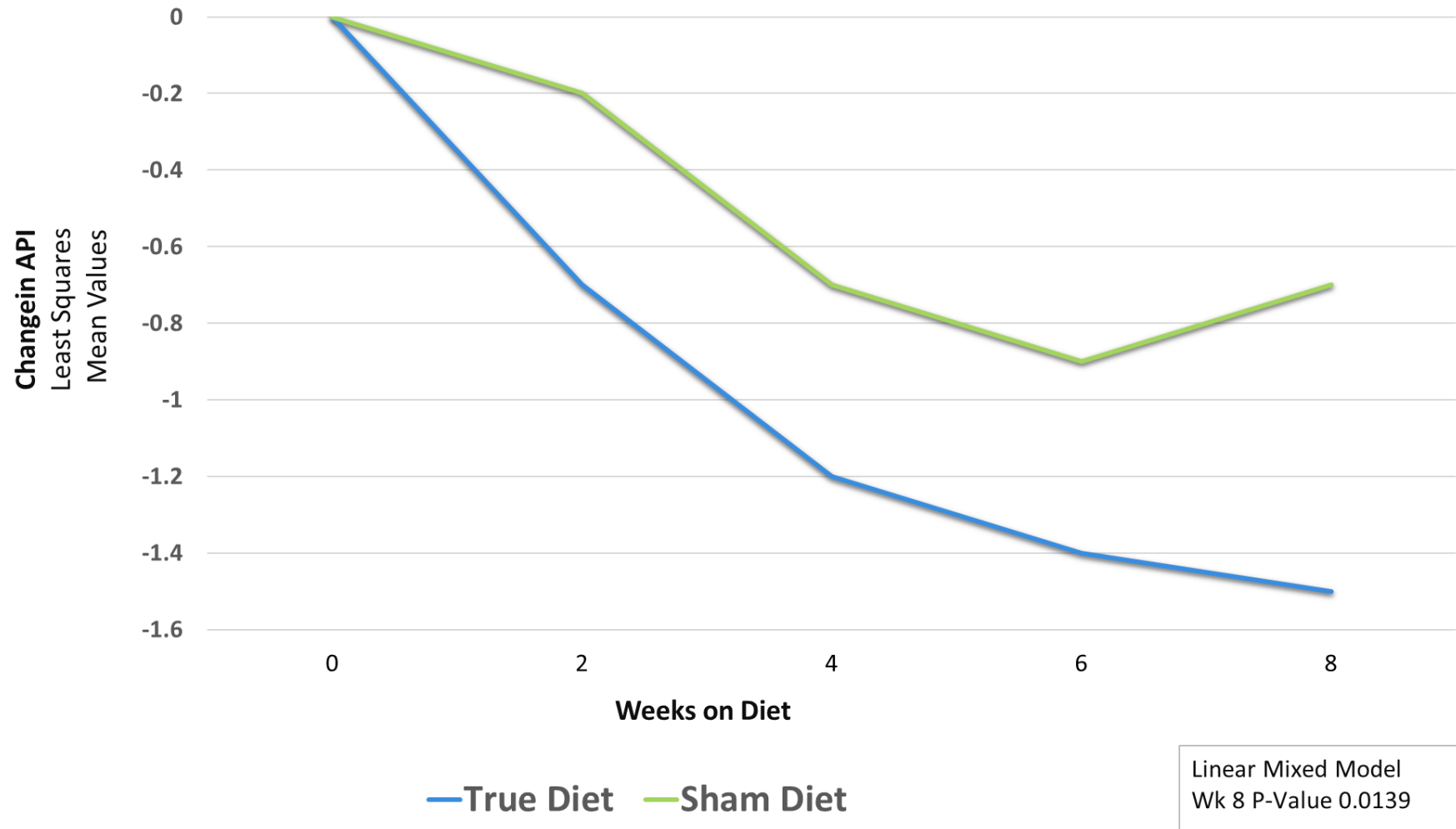
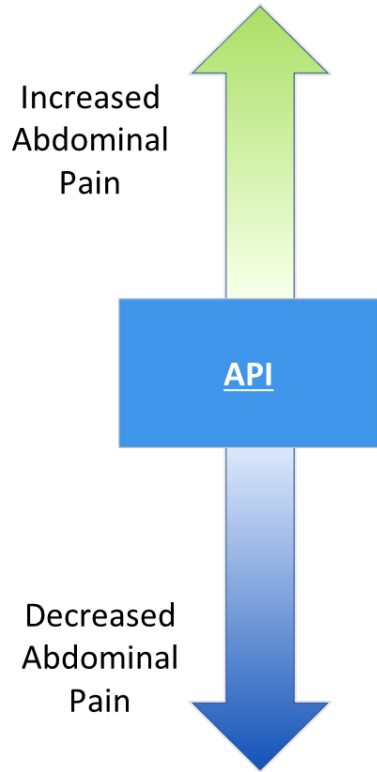
# FDA Approved Drugs are Expensive and have Efficacy and Safety Limitations

Indication	Drug	FDA Approval	Treatment Response	Placebo Response	Efficacy: Treatment minus Placebo	Monthly Cost	Annualized U.S. Sale	Limitations
IBS-C	Linzess	2012	20% - 34%	6% - 27%	7% - 14%	\$467	\$1,963M	<ul style="list-style-type: none"> <li>• Diarrhea side effect (20%)</li> </ul>
	Amitiza	2008	14%	8%	6%	\$371	\$410M	<ul style="list-style-type: none"> <li>• Indicated for women only; not for men</li> </ul>
IBS-D	Xifaxan	2015	41%	32%	9%	\$2,757 <sup>1</sup>	\$1,905M	<ul style="list-style-type: none"> <li>• Not for chronic use</li> </ul>
	Viberzi	2015	25% - 30%	17% - 16%	8% - 14%	\$1,383	\$266M	<ul style="list-style-type: none"> <li>• Abdominal pain (secondary) endpoint not met</li> </ul>
	Lotronex	2002	NA	NA	13% - 20%	\$2,240 <sup>2</sup>	\$6M	<ul style="list-style-type: none"> <li>• For women only</li> <li>• Black box warning</li> </ul>
IBS-C IBS-D IBS-M	InFoods	LDT launch	58% 58%	48% 43%	10% to 15%	N/A	New	<ul style="list-style-type: none"> <li>• No side effects</li> <li>• 10% all patients</li> <li>• 15% women only</li> </ul>

IBS Drug Side Effects Can Be Dangerous | Lotronex carries a black box warning related to the risk of potentially serious GI events



## Abdominal Pain Index (API) Change from Baseline IBS non-D Population



# InFoods® Regulatory & Commercial Pathway



→ CLIA Lab Developed Test to be launched on fiscal Q3

→ FDA has determined proposed IBS clinical study is a **non-significant risk** → De Novo

→ Recently completed Endpoint Trial results driving significant interest from physician groups

## Endpoint and Pivotal Trials Overview

### Sites

Mayo Clinic, Harvard BID, University of Michigan, Houston Methodist, University of Texas Houston & others

### Design

Double-blind randomized placebo controlled trial of true diet for foods with a positive immune response v. sham diet of random foods

### Primary Endpoint

All 9 FDA endpoints QOL, API, BSS, SSS, etc. for Endpoint Trial; one endpoint to be selected for Pivotal Trial (e.g. API)

### Participants

N=180 (Endpoint Trial); N=500-700 (Expected for Pivotal Trial)

### Complete

**Completed Endpoint Clinical Trial shows improvements in Multiple Symptoms for IBS Patients**

# Launch of InFoods IBS as LDT with Gastro Health

## New Relationship with Gastro Health (GH):

A leading gastroenterology group with over **390 employed GI physicians**. A leader in advanced innovation and technology in GI patient care .

Operates over 100 patient care centers in Alabama, Florida, Maryland, Massachusetts, Ohio, Virginia, and Washington.

InFoods IBS is now integrated into GH patient systems to facilitate doctors' **"one click" ordering** for the inFoods IBS test.

## New Groups Recently Added:

Integrated medical system that employs approximately 7,500 medical staff

The large GI group has over 90 physicians in 60 locations and offers advanced treatment options for GI diseases.

## Pilot

Pilot of inFoods® IBS with Large 1,100 Physician Group



# InFoods IBS: Whole Blood

## **inFoods® IBS: Now Validated for Use with Simple Finger Stick Whole Blood Collection Technology**

Finger stick (capillary) patient whole blood samples simplify sample collection and facilitate wider access to the test.

Any trained medical professional in the doctor's office can collect the patient's blood sample during their office visit and forward the sample to the Lab for processing.

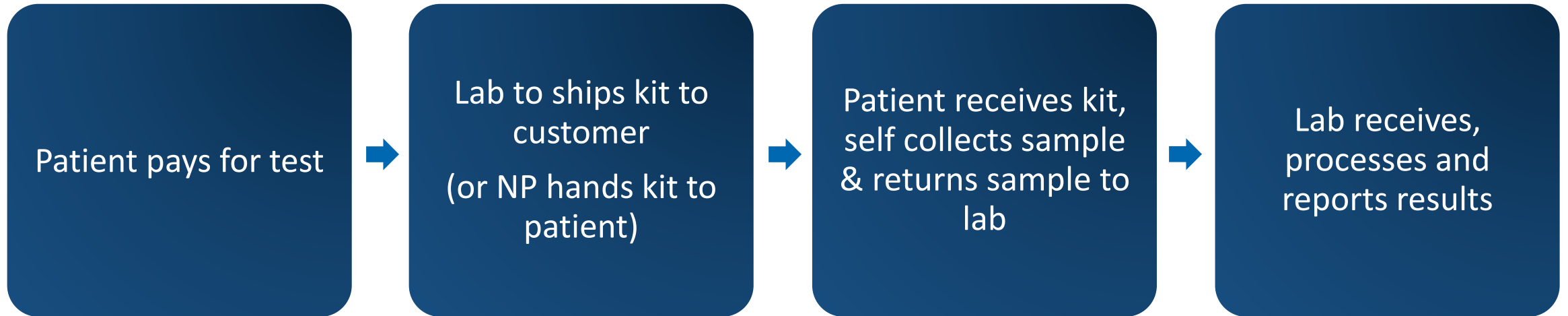
This workflow enhancement greatly simplifies the process for healthcare providers to order the inFoods IBS test and is much easier for patients



# At Home Collection & Workflow



- Simple At-Home Self Collection
- Return shipping (USPS) label included in kit
- Simple Instructions and video
- Quick Turnaround 2 to 3 weeks





# InFoods® IBS: Broad Benefits to Patients, Physicians, and Healthcare Insurers

Targets 100% of the IBS Market (IBS-M, IBS-C, IBS-D)<sup>1</sup>

## Patient Benefits

**InFoods®** targets underlying causes **without causing side effects**

vs

IBS Drugs – Primarily treat symptoms AND can cause **major side effects**

## Physician Benefits

**InFoods®: Recurring revenue potential** as problem foods change in patients

vs

IBS Drugs = \$0 revenue to physician

## Payer/insurer Benefits

**InFoods® insurer savings**  
Currently: IBS Patients require 3x doctor visits & monthly drug costs

**U.S. Healthcare annual costs of IBS ~\$30B/year**

<sup>1</sup>IBS-M = Mixed: Alternates C+D; IBS-C = Constipation; IBS-D = Diarrhea.

# InFoods® Commercialization Strategy

## Multiple Avenues to Drive Adoption

### Inclusion in Guidelines

- Inclusion in the IBS treatment guidelines will accelerate product adoption
- The Rome Foundation holds significant influence in setting the treatment guidelines
- InFoods IBS will be presented in the IBS clinical session at 2024 DDW

### Reimbursement Awareness and Enhanced Coverage

- Help GI physicians monetize their largest patient population: reimbursement code already exists for Medicare patients
- Initiate conversations with payors to enhance access to product at both the point of care and outpatient diagnostic centers

### Broad Physician Interest

- Capitalize on strong physician interest evidenced by market research<sup>1</sup>
- GI physician and PCP respondents indicated they would adopt this product for 95% - 100% of their patients, depending on the IBS subtype<sup>1</sup>

**95% GI Physicians and PCPs Would Adopt InFoods® for Their Patients Depending on Subtype**

<sup>1</sup>Market Research Source: Market Vision. Percentages shown represent medians for both GI physicians and PCPs based on the information they were presented as part of the market research survey.

# SAB: Rome Foundation- Sets IBS Guidelines Expertise in Clinical Trials



## Rome Foundation (Leading IBS organization)

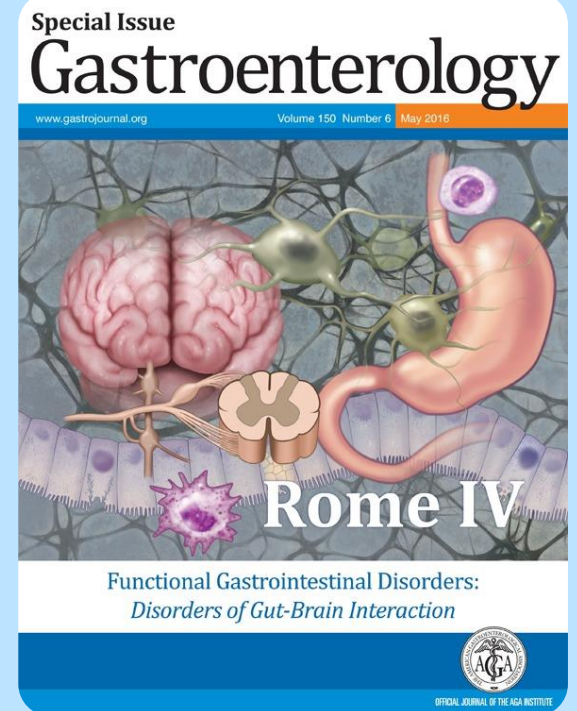
- Leading independent non-profit organization focused on the diagnosis and treatment of functional gastrointestinal disorders, including IBS
- Rome creates the diagnostic criteria and guidelines that FDA and physicians use to define an IBS patient, and treat those patients

## Dr. Doug Drossman (Biomerica SAB Chair)

- Dr. Doug Drossman (President Emeritus of the Rome Foundation) is one of the foremost opinion leaders in IBS
  - Participated in 50+ Clinical Studies for IBS

## Key Expertise on IBS Clinical Trials

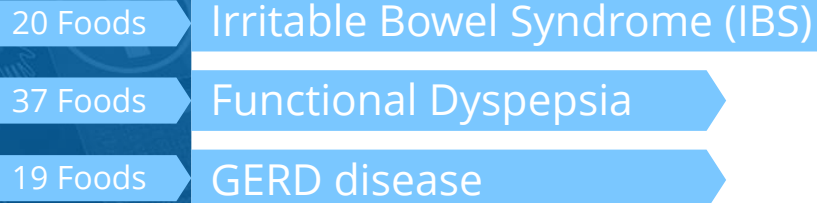
- SAB members were the PI's on clinical trials for multiple approved GI drugs, including Linzess®, Viberzi®, and Xifaxan®
- Members serve on FDA GI advisory panel



# Platform Technology:

# InFoods® Development Pipeline

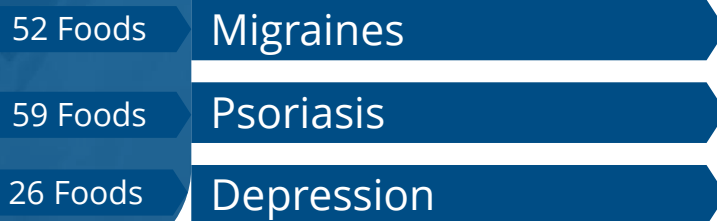
Functional  
Gastrointestinal  
Disorders



Gastrointestinal  
Diseases



Other Chronic  
Inflammatory  
Diseases



# Specialty Diagnostics

The image displays four diagnostic product cards arranged horizontally. Each card features a brand logo, product name, and key benefits. The cards are: 1. 'hp detect' Ulcer Screening Test with purple checkmarks. 2. 'ez+detect' Colon Disease Test with a blue cross and text: 'Self-test for early warning signs of colorectal disease' and 'In-home results in 2 minutes'. 3. 'aware' Breast Self Exam with a pink ribbon and text: 'FDA CLEARED' and 'EARLY DETECTION IS YOUR BEST PROTECTION'. 4. 'fortel' Prostate (PSA) Screening Test with orange checkmarks and text: 'EARLY DETECTION IS YOUR BEST PROTECTION'.

**hp detect**  
ULCER  
SCREENING  
TEST

**ez+detect**  
COLON  
DISEASE  
TEST

Self-test for early warning  
signs of colorectal disease

**In-home results in 2 minutes**

**aware**  
BREAST  
SELF  
EXAM

FDA CLEARED

EARLY DETECTION IS  
YOUR BEST PROTECTION

**fortel**  
PROSTATE  
(PSA)  
SCREENING TEST

EARLY DETECTION IS  
YOUR BEST PROTECTION



# 2024 Growth opportunity - H. pylori

hp detect™

*Detects H. pylori Antigen*

**H. pylori** is a bacteria that infects approximately 35% of the U.S. population and 45% of the population in the five major countries in the Europe. Approximately 20% of *H. Pylori* infected patients develop a range of issues including peptic ulcer disease, dyspepsia and gastric cancer.

→ **Status:** Biomerica received **FDA 510K clearance**

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→ **Gastric Cancer:** Gastric cancer is the 3rd most common cause of cancer related death in the world. Over 80% of gastric cancers are attributed to *H. pylori* infection. In 2017, the World Health Organization (WHO) listed *H. pylori* among the 16 antibiotic-resistant bacteria that pose the greatest threat to human health and designated *H. pylori* as a Class 1 carcinogen.

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→ **Profit Opportunity:** Biomerica H. pylori product has clinical and economic benefits while being able to be sold at a significant discount to competitive products.

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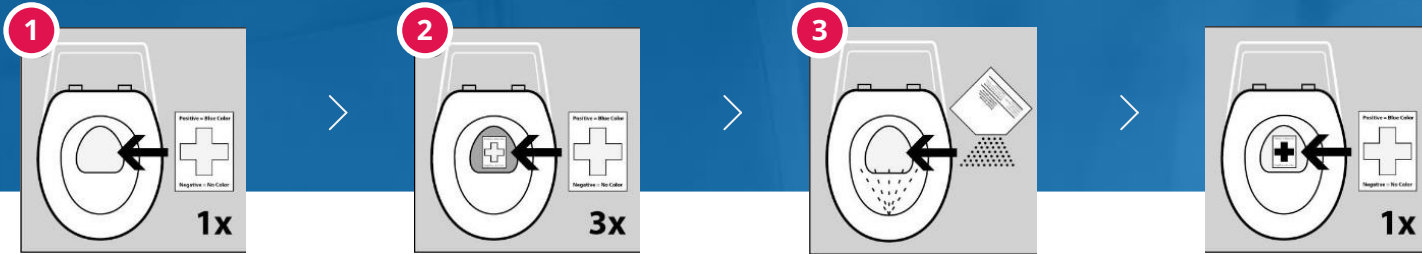
→ **Customers:** The majority of H. pylori diagnostic tests are sold to large labs such as Quest, LabCorp and ARUP. Therefore, less marketing effort is needed to achieve material market penetration.

# Colorectal Disease Test: EZ Detect™

EZ Detect is a 2-minute, at-home test for the determination of fecal occult blood, an early warning sign of colorectal cancer (CRC) and other colorectal diseases.

Quick & Simple:

## No Stool Handling



### Interpretation



Negative

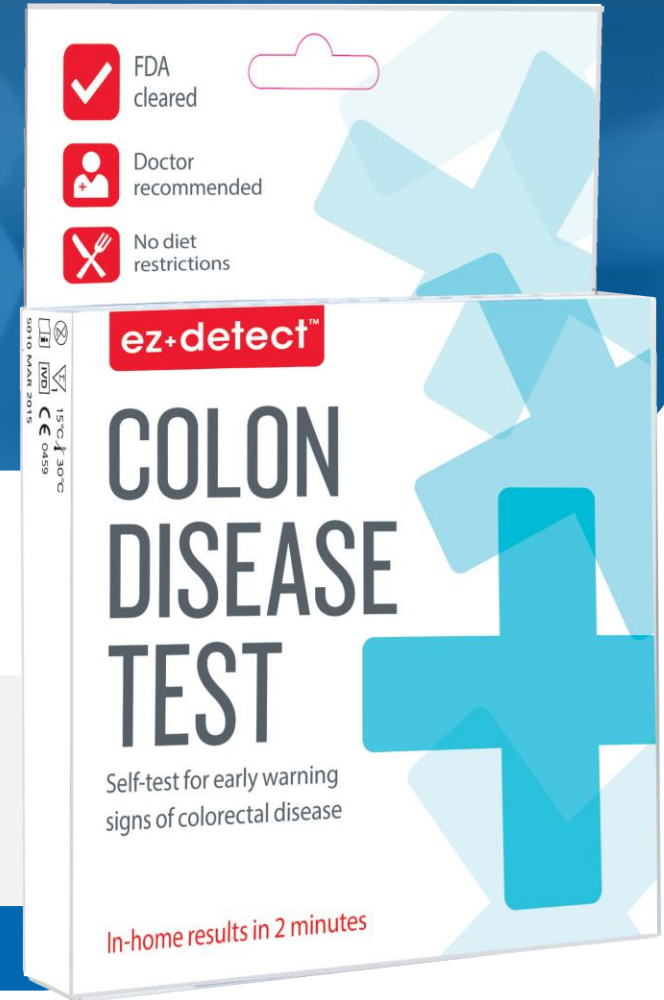


Positive



Positive

Any color in the test area (no matter how small) should be considered as a positive result

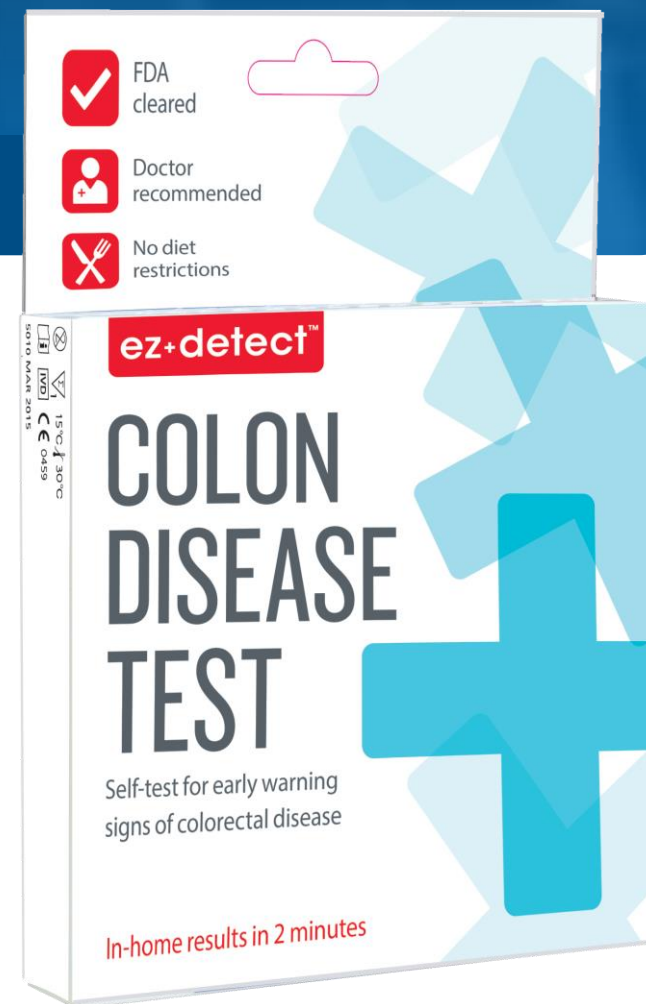


# Key performance metrics for EZ Detect™, Cologuard® , & FITs

Value	EZ Detect™ (1)	Cologuard® (2)	FIT (2)
Price	\$14	\$649	\$22
Accuracy	93.2%	86.6%	94.7%
Positive Likelihood Ratio	91.2	6.9	14.3
Negative Likelihood Ratio	0.27	0.09	0.28
Specificity (vs. all negative findings on colonoscopy/sigmoidoscopy)	99.2% (124/125)	86.6% (7936/9167)	94.9% (8,695/9167)
Sensitivity (vs. all CRC found by colonoscopy/sigmoidoscopy)	72.9% (27/37)	92.3% (60/65)	73.8% (48/65)
Negative Predictive Value	92.5% (124/134)	99.9% (7936/7941)	99.8% (8695/8712)
Positive Predictive Value	96.4% (27/28)	4.6% (60/1291)	9.2% (48/520)

(1)Results of the Study (Screening) Conducted by Renfe's Medical Department. 2000.

(2)Multitarget Stool DNA Testing for Colorectal-Cancer Screening. Imperiale, Thomas F, et al. 2014, The New England Journal of Medicine, Vol. 370, pp. 1287-1297.



# Aware® Breast Self Exam

aware®

- **FDA – Cleared and CE Mark**
- The Aware® Pad is as an aid for performing at-home breast self-examination
- About **80% of breast cancers** are **detected because women themselves notice changes** in their breasts<sup>1</sup>
- Recurrent purchases and several pads for female family members

1. <https://www.pinkribbon-deutschland.de/vorsorge-fakten/fakten>, accessed 02 AUG 2022



## Clinical Study Kawasaki Medical University Hospital for Aware FDA approval (N=832 Patients)

→ Study concluded that **Aware<sup>®</sup>** is a highly effective tool for early detection of breast abnormalities

→ Regular practice of Breast Self Exam is extremely important for early cancer detection

### Detection Ratios

	Breast Cancer	Fibroma Biopsy Case / Non-Biopsy Case	Mastitis Biopsy Case / Non-Biopsy Case	Non-Tumor
Patient	98.6%	90.9%/87.8%	86.4%/65.2%	9.8%
Nurse	100%	96.0%/92.0%	86.4%/58.2%	4.8%

# Prostate (PSA) Screening Test

fortel

→ The Fortel® Prostate (PSA) Screening test is a simple at-home visual test to **detect elevated levels of Prostate Specific Antigen (PSA)** using a finger prick blood sample

→ Laboratory accuracy in the comfort of your home

→ Results in 10 minutes

**Prostate (PSA) screening made easy.**





# Laboratory Accuracy

## Clinical Study #1 Performance vs. Reference Method (Immulite 2000/ Abbott AxSYM Total PSA /Roche E170 tests)

**Sensitivity: 100%**

**Specificity: 95%**

**Accuracy: 97.5%**

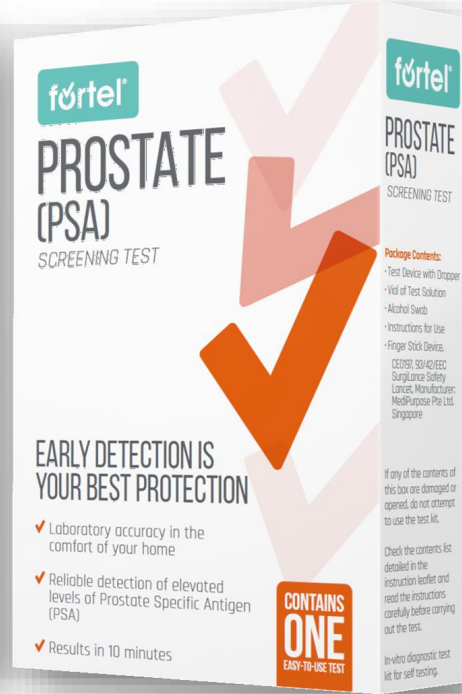
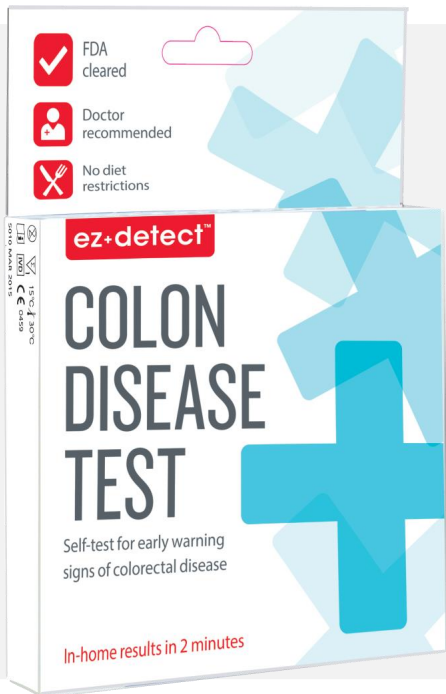
		Reference Method		
		Positive	Negative	Total
Fortel® Prostate (PSA) Screening Test	Positive	80	4	84
	Negative	0	77	77
	Total	80	81	161

- Clinical studies for PSA were performed using 161 clinically confirmed samples.

ez+detect™

aware™

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## Insurance reimbursement & distribution

ez+detect™

aware™

New multi-year exclusive distribution agreement with leading UAE healthcare company recently signed

Dubai Government Grants Insurance Reimbursement for EZ Detect

In discussions with other governments for Insurance Reimbursement in UAE and other MENA countries

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Fortel® Prostate PSA received approval from the Kingdom of Saudi Arabia

# Leveraging Our Unique Technology



## Disruptive Patented Platform Technology redefining the GI Market

Addressing the large need for IBS patients and then targeting multiple other diseases



## InFoods Model is Unique

Benefits Patient / Physician / Insurer



## Broad IP Protection

Robust patent portfolio (35 issued patents; 100+ patents pending)

- 15+ year remaining on patents filed
- Patents cover multiple disease states



## Financially Attractive

- Low burn rate
- Clean Cap table - No warrants, no preferred equity and no debt



## IBS Key Opinion Leaders set Treatment Guidelines

- SAB Leadership includes US Members of the Rome Foundation
- Clinical studies lead by principal investigators who set GI “treatment guidelines”