BiomeDx

Advancing cancer therapy through microbiome profiling

www.biome-dx.com

FINANCIAL TIMES · Frankfurter Allgemeine · SECURITY INSIDER · ClinicumOnko · Pro Sieben · trend. · Healthcare DIGITAL · onkologie · doctors today

In a nutshell

BiomeDx

We develop NextGen medical products based on clinical profiling of the microbiome

Clinical studies	Collected microbiome profiles	Top-tier collaborations
19	> 65.000	

cost EUROPEAN COOPERATION IN SCIENCE & TECHNOLOGY

Group leader at ML4Microbiome

ML4 MICROBIOME

23 FTEs, 8 nationalities, 9 languages

BiomeDx

Award winning company

web summit

EYSCALEUP

CATAPULT

eit Health

Barbara Sladek, PhD, MBA

Dr. Nikolaus Gasche

Some cool facts

AWARD 23 — Entrepreneur of the Year

SIEMENS Healthineers — Business Unit Manager

intelliSEC GmbH — Successful exit

Forbes 30u30 — Forbes 30u30

Board members

Wiener Gesundheitsverbund

KÄLLA

Education

University of Oxford

universität wien

Med Uni Graz

What does Biome Diagnostics do?

BiomeDx

Advancing healthcare through microbiome-profiling

Artificial Intelligence

Data Science

Stool Test

Microbiome Diagnostics

With one stool sample, the most advanced next-sequencing methods and state-of-the-art artificial intelligence paired with bioinformatics, we enable the most accurate analysis of the intestinal microbiome. With the information from the individual microbiome profile, we can derive information that enables us to make statements about disease progression and the effectiveness of therapeutic methods.

Technology and innovation

BiomeDx

Complete digital microbiome end-to-end service

Next Generation Sequencing

+

Bioinformatics with machine learning algorithms

+

Proprietary knowledge database

+

Advanced algorithms for diagnostics

ISO 9001:2015

ISO 13485:2016

HL7 International

The intestinal microbiome plays a major role

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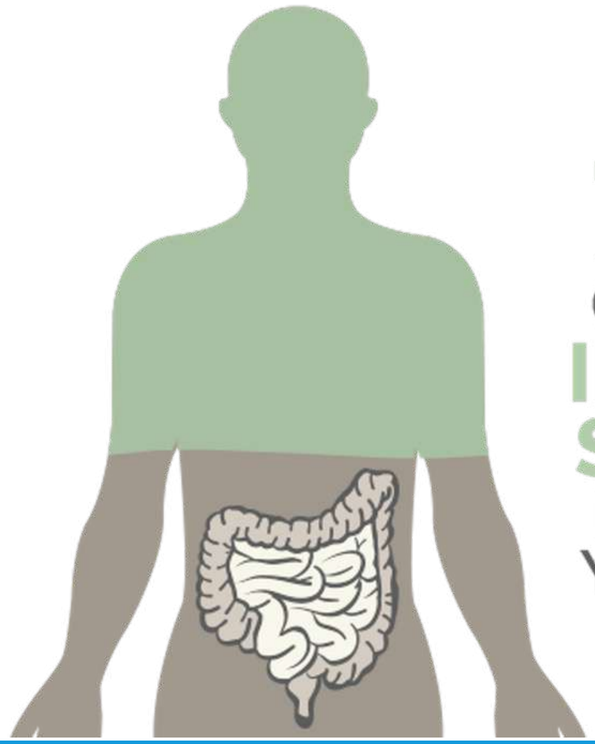
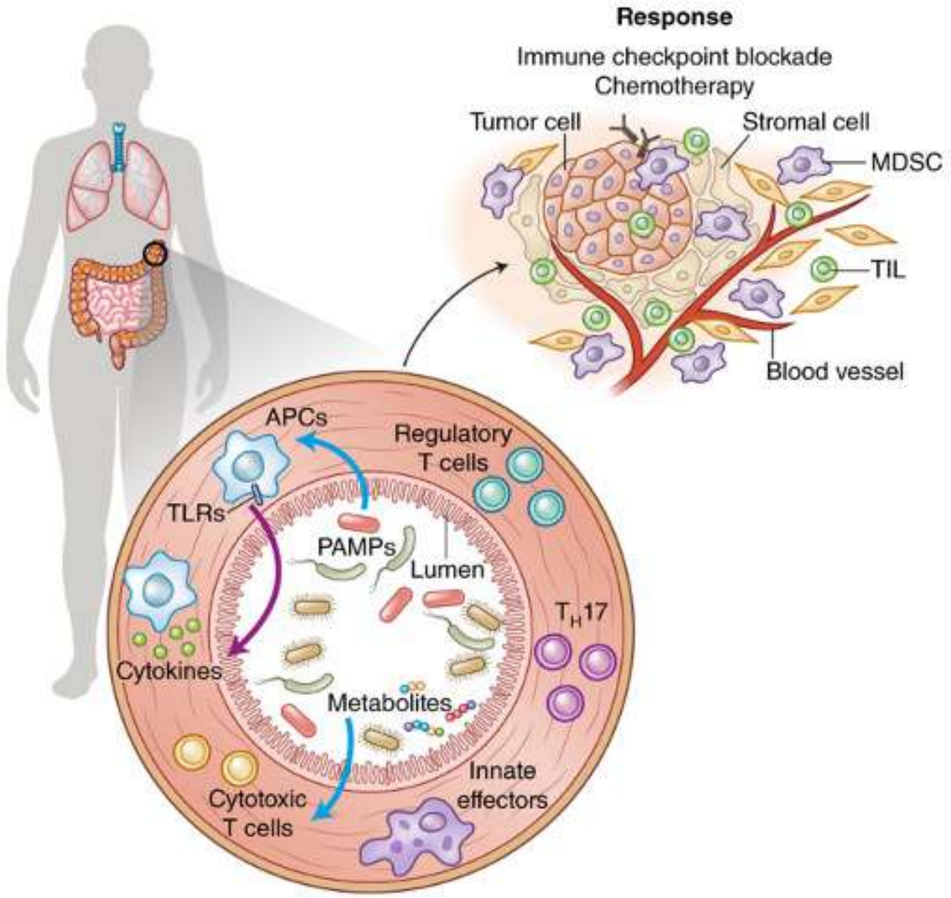
A healthy gut microbiome is associated with improved therapeutic success and fewer side effects in oncology

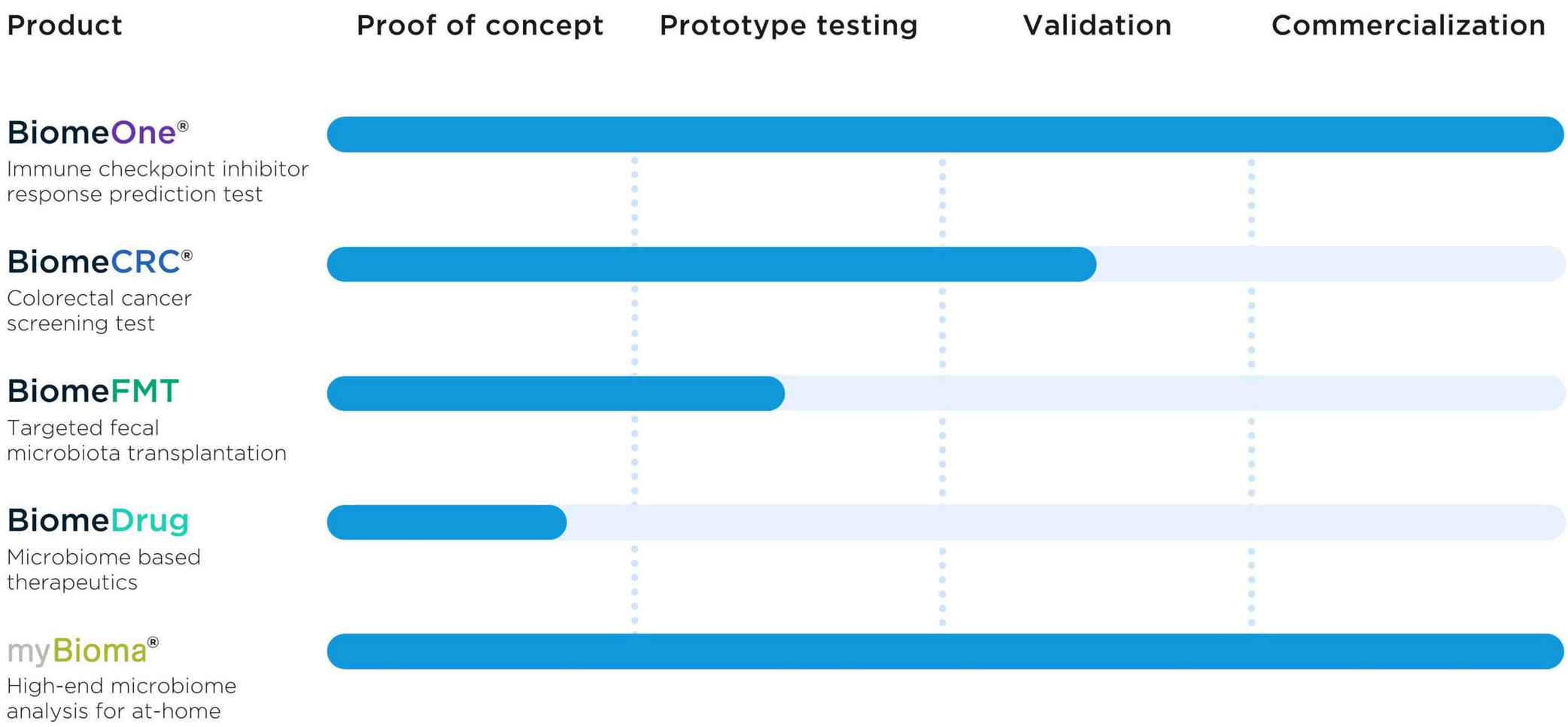


70%
OF YOUR
IMMUNE SYSTEM
EXISTS IN
YOUR GUT



Pipeline

BiomeDx



myBioma® - the digital microbiome solution

BiomeDx

Because your health starts in the gut

- Scientific microbiome analysis for at-home
- Microbiome insights on:
  - Diversity
  - Enterotype
  - Associations
  - Pathways
  - etc.

- Available in Europe
- > 300 partner therapists
- +40 white-label partners

Further explorative analyses

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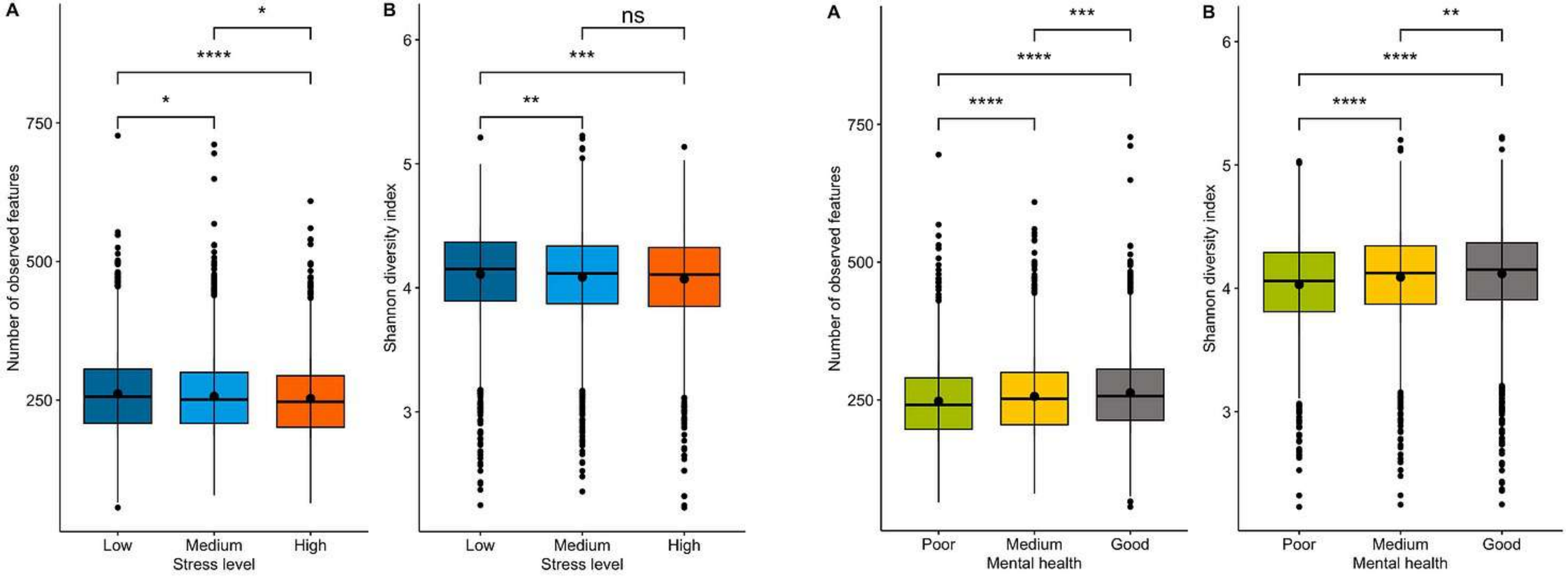
Impact of microbiome on psychological health, stress and depression (n=7,957)

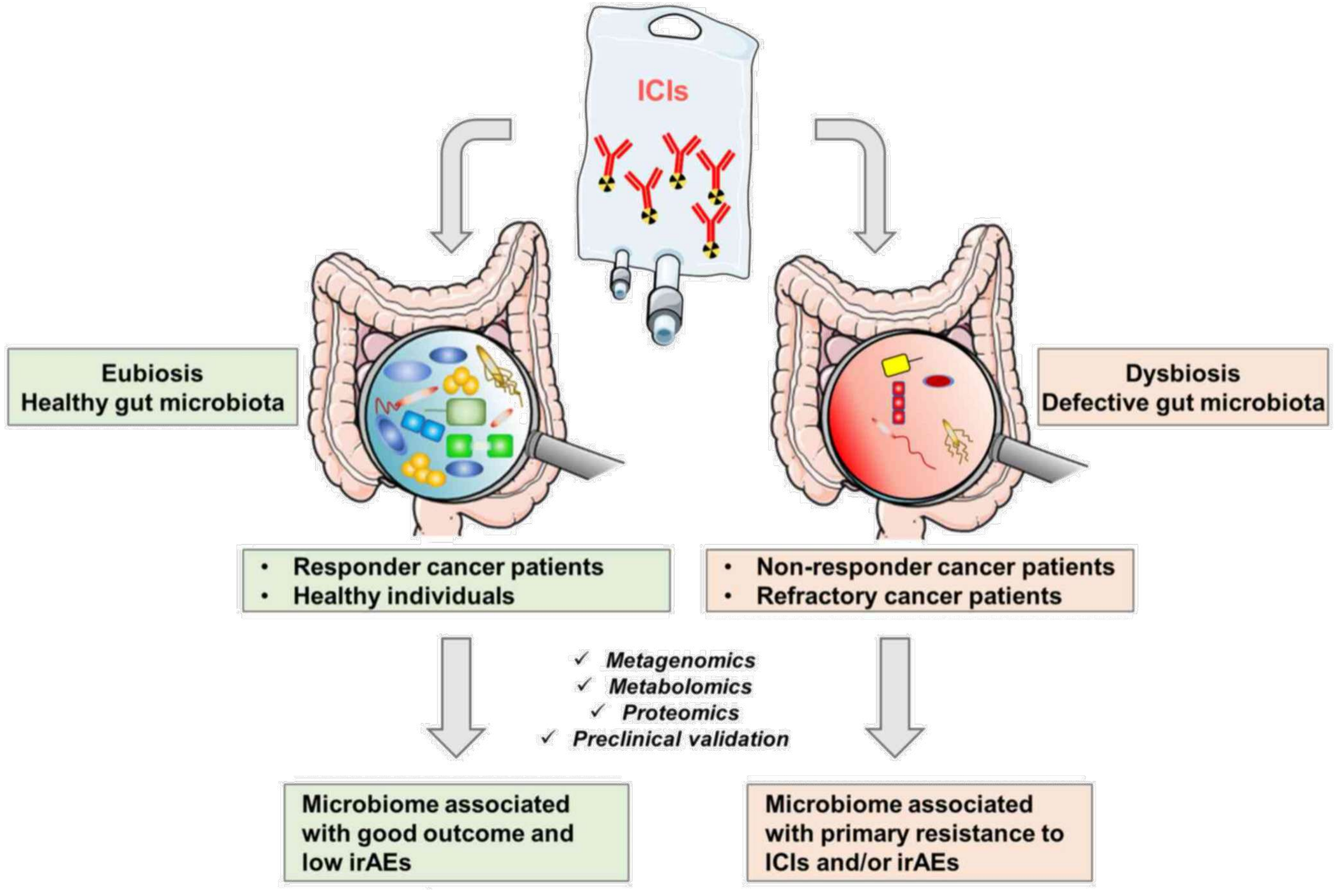


Oncology and gut microbiome

Gut microbiome modulates response to immune checkpoint inhibitor therapy

The composition of the gut microbiome can be used to predict therapeutic success.

A healthy gut microbiome may be associated with improved therapeutic success and fewer side effects.



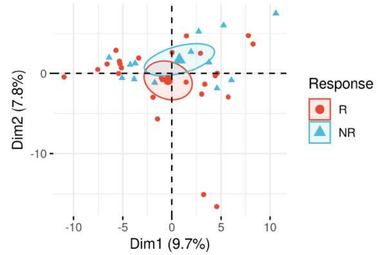
Reference: Vivarelli et al. Int J Oncol. 2021

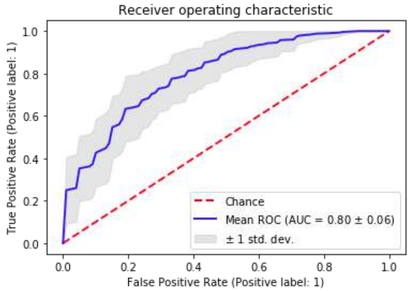
BiomeOne® - First microbiome diagnostic

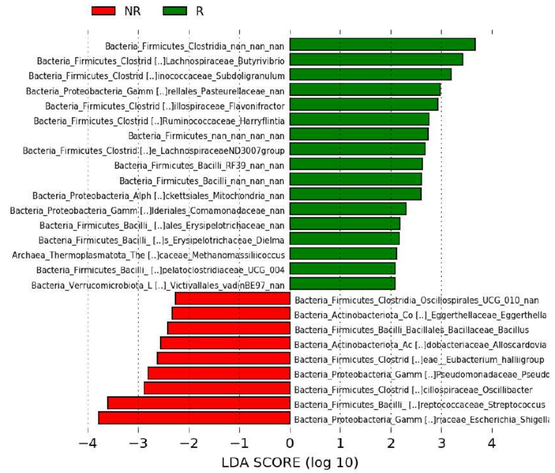
BiomeDx

Immunotherapy response prediction test

- ✓ Predicts response & tolerability to immunotherapy
- ✓ Reliable across multiple tumour types
  - Melanoma
  - Non-small cell lung cancer
  - Renal cell carcinoma
- ✓ Non-invasive & performed on a single stool sample
- ✓ Microbial pattern of 80+ bacteria







Available as medically certified in-vitro diagnostic! CE IVD

Cancers (Basel). 2023 Jul; 15(13): 3268. PMCID: PMC10339964

Published online 2023 Jun 21. doi: 10.3390/cancers15133268 PMID: 37444378

Assessing the Performance of a Novel Stool-Based Microbiome Test That Predicts Response to First Line Immune Checkpoint Inhibitors in Multiple Cancer Types

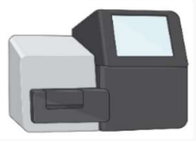
BiomeOne biomarker development

Dataset

Over **10.000 patients worldwide** were used for the biomarker development (20% cancer patients)

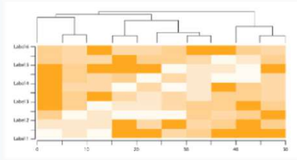
Partnered studies + Proprietary data + Public data

Microbiome data



Next-Generation Sequencing

Bioinformatics



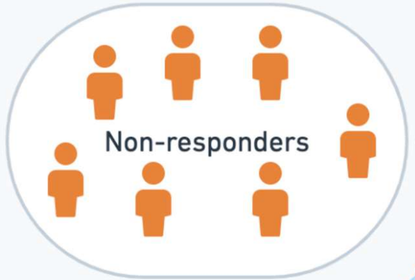
1400 different species identified

Biomarker identification

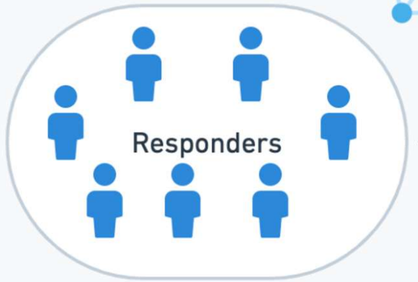
Clinical data

- Response
- Immune-related adverse events
- Tumor type
- Gender, country, age, diet

Data analysis

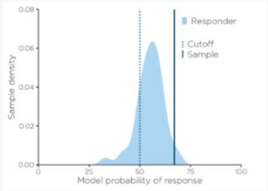


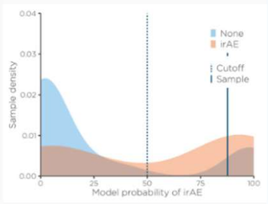
Classification algorithm to distinguish response



Approx. 15 million data points included in the calculation

BiomeOne validation



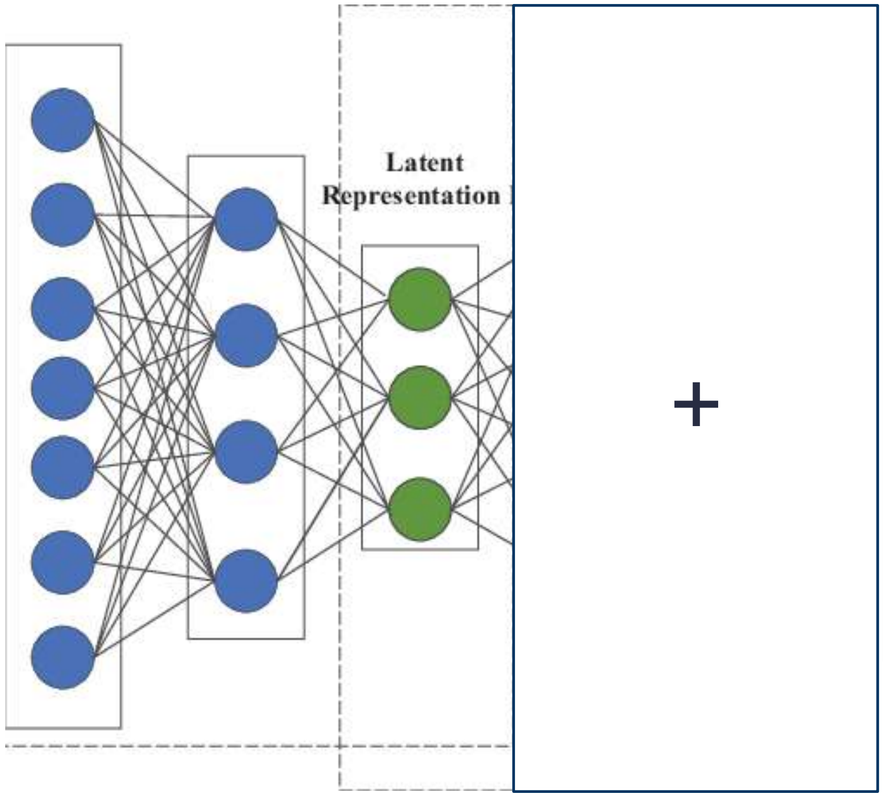


Validation through multi-centric study (5 centres) with **III/IV patients** (melanoma, NSCLC, renal cell carcinoma)

Sensitivity: 81%
+20% compared to current gold standard

Clinical application
ICI-response prediction
irAE prediction
FMT selection

Dimensionality reduction & final model



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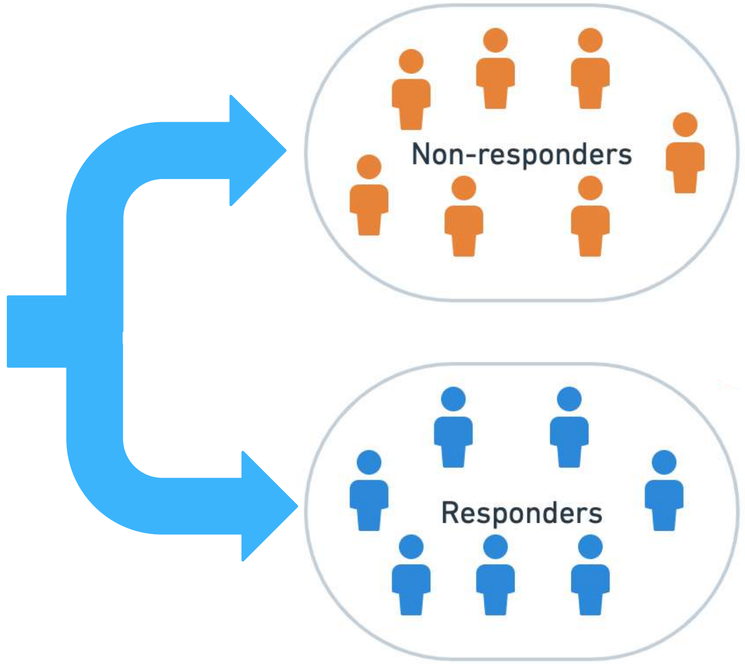

Training data autoencoder:
Cancer patient datasets
Healthy customer datasets

Training & validation data random forest:
Cancer patient datasets (compressed)

BiomeOne validation study

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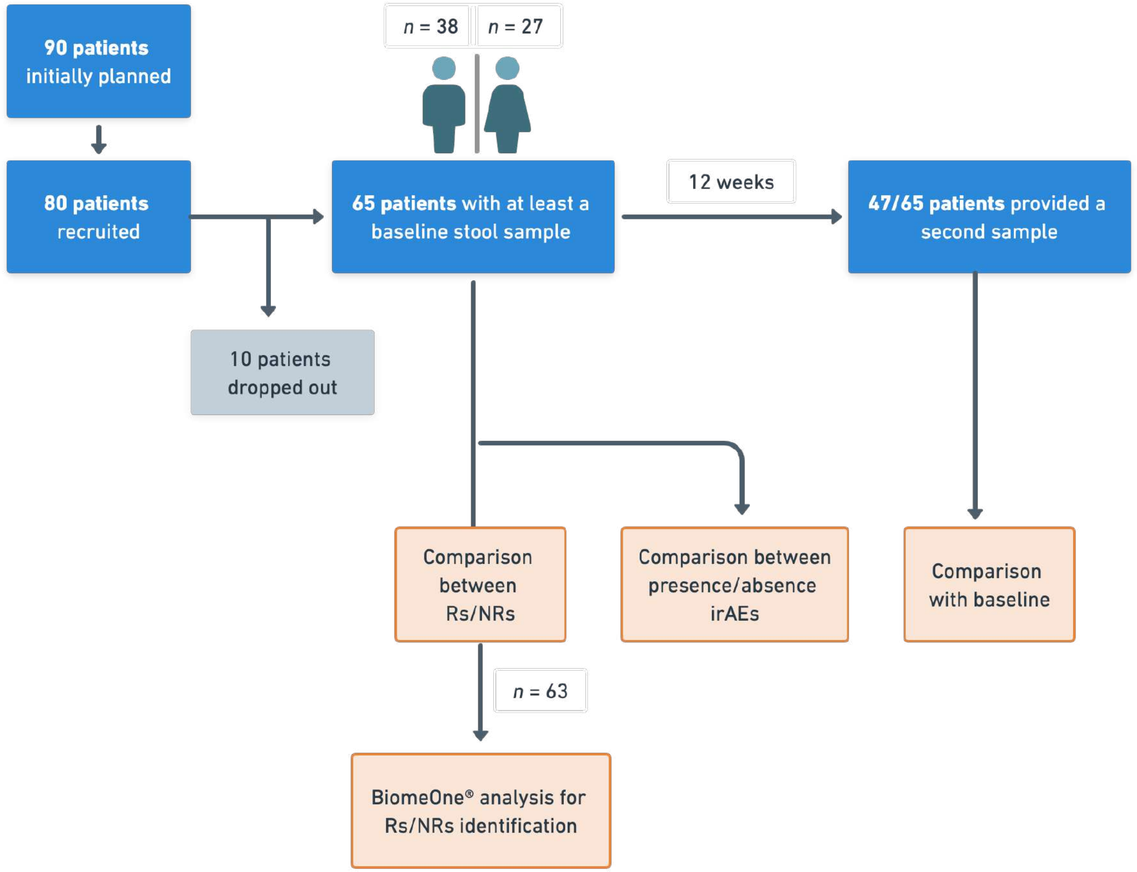
Longitudinal analysis of stool microbiome samples in melanoma, RCC and NSCLC patients (stadium3b/4)



Prim. Priv.-Doz. A. Valipour,
OA Dr. M. Hochmair

Prof. M. Schmidinger

Priv Doz. E. Richtig

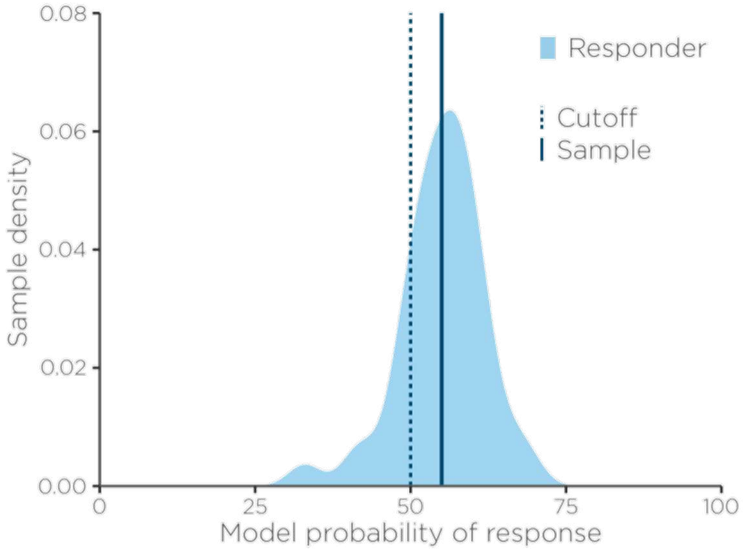
Priv. Doz. G. Absenger,
Assoz. Prof. M. Pichler

Prof. V. Nguyen

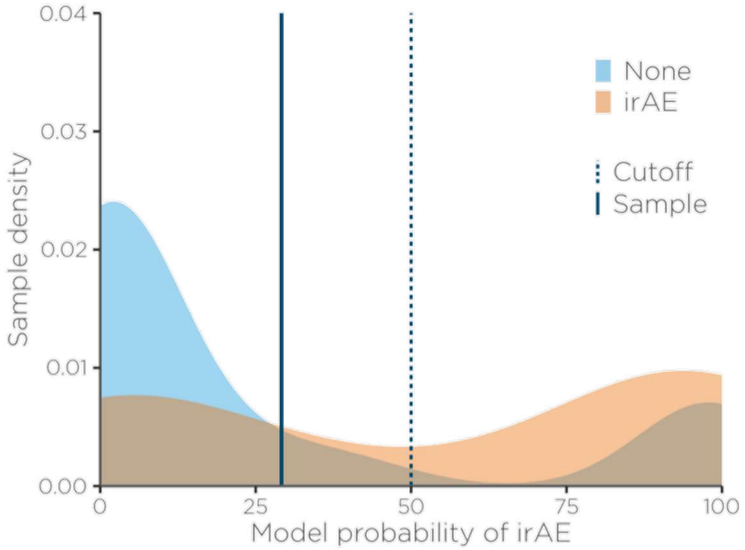
BiomeOne report

BiomeDx

Probability of response: high



Probability of irAEs: low



Clinical response

The analysis of the intestinal microbiome reveals a high probability (55%) of the occurrence of a response to a checkpoint inhibitor based cancer immunotherapy (CTLA-4, anti-PD-1 or anti-PD-L1).

Please note: The values 0 - 50 % represent a low probability of the occurrence of a response. The values 51 - 100 % represent a high probability of the occurrence of a response.

Tolerability (irAEs)

The analysis of the intestinal microbiome reveals a low probability (29%) of the occurrence of immune-related adverse events (irAEs) of any grade during a checkpoint inhibitor based cancer immunotherapy (CTLA-4, anti-PD-1 or anti-PD-L1).

Diversity

5.98

Normal range: 5.62 - 6.42

Bacterial richness

375

Normal range: 202 - 320

Enterotype

1

Regulatory and QM challenges

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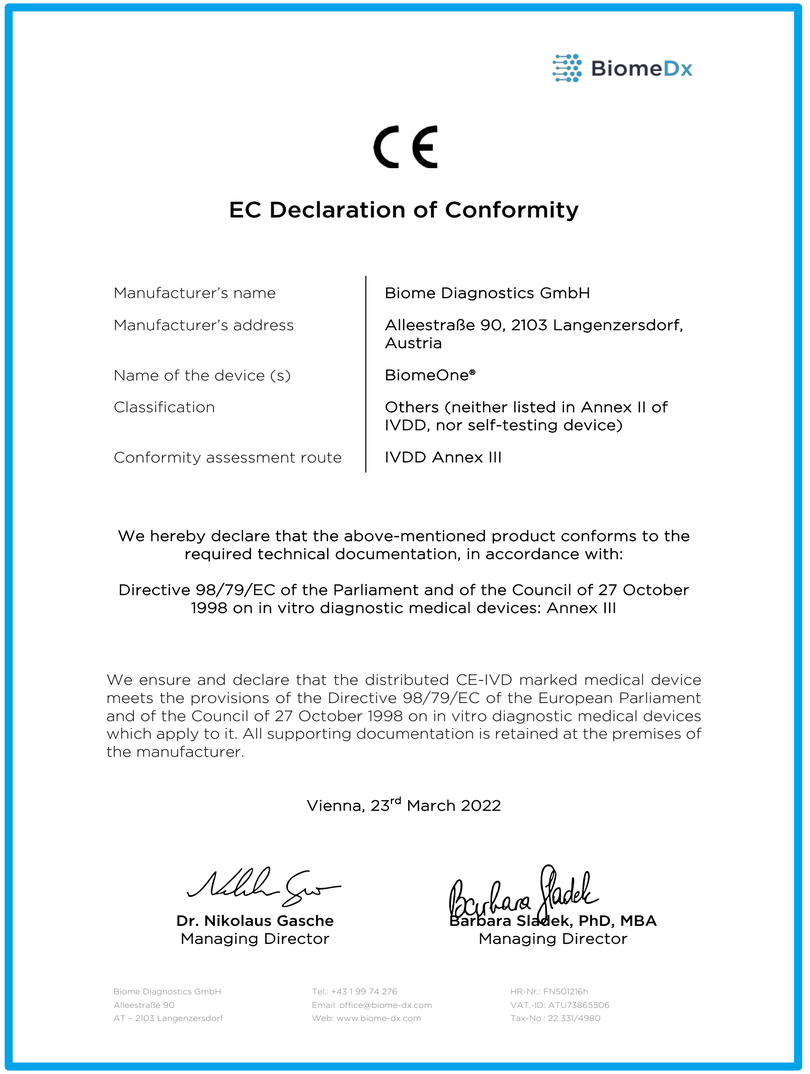
BiomeOne CE-IVD registered medical device

- **Regulatory Requirements**
- IEC 62304:2006 Software Life Cycle process
- ISO 14971:2019 Risk Management
- ISO 13485:2016 & ISO 9001 eQMS – electronic Quality Management System
- EN 62366_1:2015+A1:2020 Usability Engineering Processes
- MDCG Guidances

- **New Challenges**
- Further indications
- Improvement of machine learning model



BiomeDx

CE

EC Declaration of Conformity

Manufacturer's name	Biome Diagnostics GmbH
Manufacturer's address	Alleestraße 90, 2103 Langenzersdorf, Austria
Name of the device (s)	BiomeOne®
Classification	Others (neither listed in Annex II of IVDD, nor self-testing device)
Conformity assessment route	IVDD Annex III

We hereby declare that the above-mentioned product conforms to the required technical documentation, in accordance with:

Directive 98/79/EC of the Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices: Annex III

We ensure and declare that the distributed CE-IVD marked medical device meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices which apply to it. All supporting documentation is retained at the premises of the manufacturer.

Vienna, 23rd March 2022

Dr. Nikolaus Gasche
Managing Director

Barbara Sladek, PhD, MBA
Managing Director

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HR-Nr.: FN501216h
VAT.-ID: ATU73865506
Tax-No.: 22 331/4980

The future: Binary model on adenoma prediction

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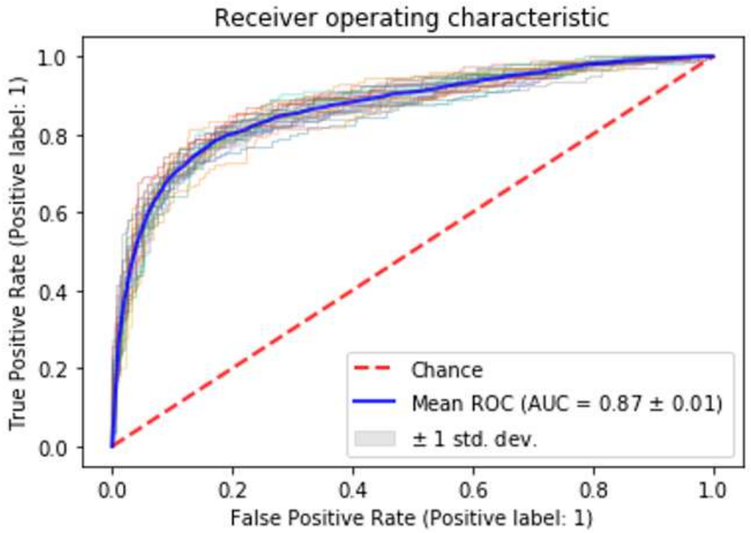
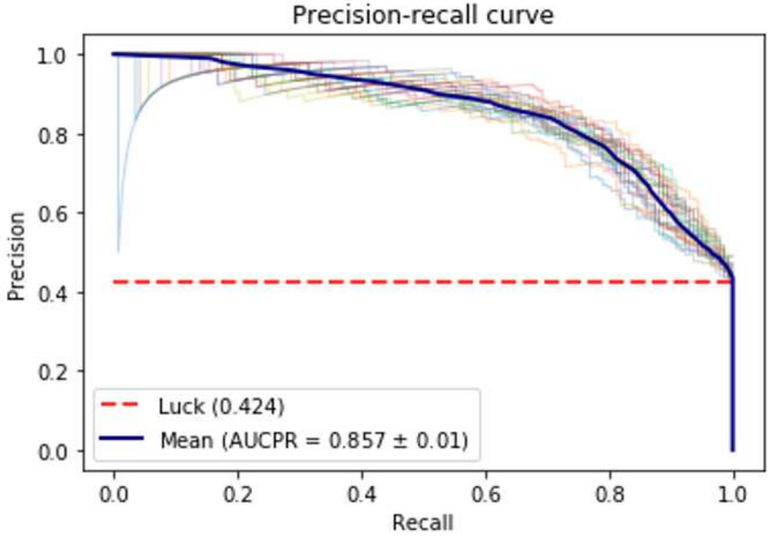
transformation	subsampling depth	feature selection	model	outlier exclusion	AUC	sensitivity	specificity
						0.68	0.91





BiomeCRC®

Colorectal cancer screening test

Publications & posters

- Cancers 2023: Assessing the Performance of a Novel Stool-Based Microbiome Test That Predicts Response to First Line Immune Checkpoint Inhibitors in Multiple Cancer Types
- CIMT 2023: Application of the microbiome-based prediction test BiomeOne quantifies antibiotic, geographical and health-related effects on response to cancer immunotherapy in a large European cohort
- Gut Microbes 2023: Using fecal immmunochemical cartridges for gut microbiome analysis within a colorectal cancer screening program
- Gut Microbes 2022: Atypical enteropathogenic E. coli are associated with disease activity in ulcerative colitis
- DGHO 2022: BiomeOne®: multi-centric validation of a novel microbiome-based test to predict response to cancer immunotherapy
- UEG 2022: Analysis of colorectal cancer and adenoma microbiome signatures and the application of machine learning classification as a potential screening tool
- ÖGP 2022: Prediction of immune checkpoint inhibitor response in non-small cell lung cancer patients using a microbiome-based biomarker
- ÖGMBT 2022: Deconfounding the intestinal microbiome signature of responders versus non- responders to immune checkpoint inhibitor therapies
- ESMO 2022: BiomeOne: Multi-centric validation of a novel microbiome-based biomarker to predict response to cancer immunotherapy
- ÖGGH 2022: Analysis of colorectal cancer and adenoma microbiome signatures and the application of machine learning classification as a potential screening tool
- ARES 2022: Distance-based Techniques for Personal Microbiome Identification
- Data and Applications Security and Privacy 2022: Utility and Privacy Assessment of Synthetic Microbiome Data
- WCLC 2022: Introducing “BiomeOne”, a microbiome-based biomarker to predict immune checkpoint inhibitor response in NSCLC patients
- Sci Rep 2022: Shift of dietary carbohydrate source from milk to various solid feeds reshapes the rumen and fecal microbiome in calves
- ÖGP 2021: Meta-analysis on the specificity of microbiome-based signatures for predicting immune checkpoint inhibitor therapy response in non-small cell lung cancer patients

Advancing cancer therapy through microbiome profiling

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