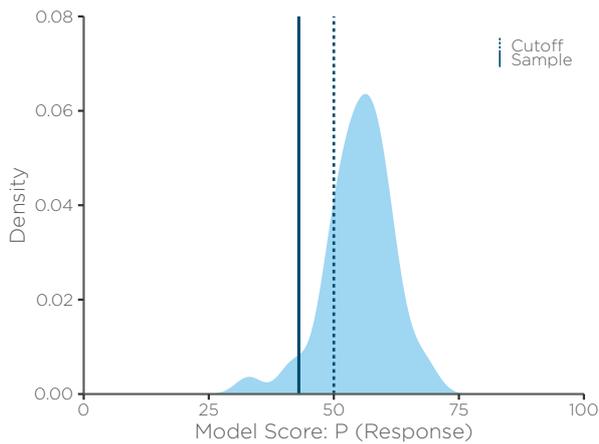
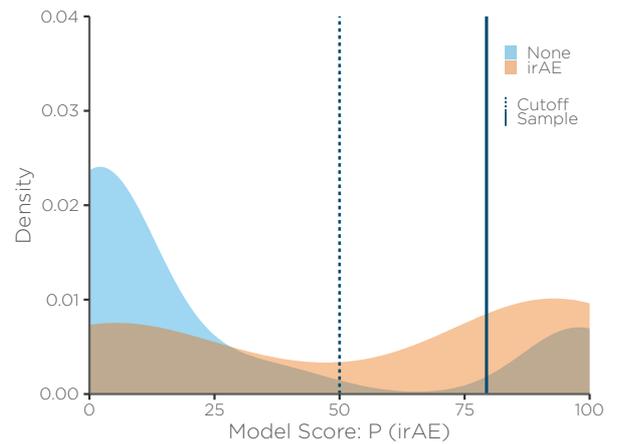


BiomeOne Microbiome Analysis

Probability of response: low



Probability of irAEs: high



Clinical response

The analysis of the intestinal microbiome reveals a low probability (43%) 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 high probability (79%) 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).

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

Diversity

6.12

Normal range: 5.62 - 6.42

Bacterial richness

243

Normal range: 202 - 320

Enterotype

3

Patient

Gender

Male

Date of birth

18 February 1951

Cancer type

Melanoma

Sample

Sample ID

12345678

Material

Stool

Sampling

Norgen Biotek

Status

Laboratory

Medical University of Vienna

Laboratory on

16 November 2021

Analysed on

10 December 2021

Disclaimer: The results in this report refer exclusively to the analysis of the intestinal microbiome. Whether a patient benefits from cancer immunotherapy with checkpoint inhibitors depends on several factors. Therefore, the results serve as additional information for the treating physician and should not be used as the sole basis for any treatment decision. Any treatment decision remains entirely the responsibility of the attending physician.

Name

Rod Warwick

Date of birth

18 February 1951

Cancer type

Melanoma

Doctor

Dr. Jordan Bradford

Report from

10 December 2021

Analytics

Clinical response

Result: low

The parameter "clinical response" describes the probability with which a patient will respond to a checkpoint inhibitor based cancer immunotherapy (CTLA-4, anti-PD-1 or anti-PD-L1). The classification is solely based on the analysis of the intestinal microbiome of the patient.

The intestinal microbiome has a significant influence on several immune-related functions of the human organism. Recent studies have shown that the intestinal microbiome is able to modulate the effectiveness of cancer therapies, especially the response to therapy with checkpoint inhibitors.

Tolerability (irAEs)

Result: high

Tolerability describes the probability with which a patient is likely to experience immune-related adverse events (irAEs) of any grade during an immune checkpoint inhibitor based therapy (CTLA-4, anti-PD-1 or anti-PD-L1). The classification is solely based on the analysis of the intestinal microbiome of the patient.

Recent studies have shown a correlation between the abundance of certain intestinal bacteria and the occurrence of irAEs in patients during cancer immunotherapy.

Diversity

Result: 6.12

The diversity describes the bacterial richness in the intestine and how well the different bacterial species are evenly distributed. The more different bacterial

types are evenly distributed, the greater the diversity. Many studies have shown that a low diversity of the intestinal microbiome can be associated with numerous diseases. Recent studies confirm that patients with higher diversity are more likely to benefit from a checkpoint inhibitor based cancer immunotherapy (CTLA-4, anti-PD-1 or anti-PD-L1).

Bacterial richness

Result: 243

Bacterial richness describes the number of different bacterial species in a given microbiome sample. A large number of different bacterial species is an indicator of a wide spectrum of metabolic and immune-related functions performed by the bacteria. Recent studies have shown that greater bacterial richness correlates with a better clinical response to cancer immunotherapy.

Enterotype

Result: 3

An enterotype describes a classification of the intestinal microbiome based on the bacteriological composition into three distinct types: Type 1 (Bacteroides), Type 2 (Prevotella), Type 3 (Ruminococcus). The decisive factors for classification are mainly genetic factors and dietary habits.

For example, a person who consumes a lot of protein and animal fats often has enterotype 1, and a person who eats more carbohydrates and fibre-rich food often has enterotype 2. Enterotype 3 is mainly found in people with a balanced diet.

Name

Rod Warwick

Cancer type

Melanoma

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18 February 1951

Doctor

Dr. Jordan Bradford

Report from

10 December 2021

Bacteria list

In this bacteria list, all bacterial genera found in the microbiome sample are listed. The abundance describes the frequency (%) with which a bacterium occurs in the sample.

Phylum	Genus	Abundance (%)	Reference (%)
Euryarchaeota	Methanobrevibacter	0.01 ↑	0.00 - 0.00
Thermoplasmata	Methanomassiliicoccus	0.00	0.00 - 0.00
Thermoplasmata	Candidatus Methanomethylophilus	0.00	0.00 - 0.00
Actinobacteriota	Actinomyces	0.00	0.00 - 0.00
Actinobacteriota	Arcanobacterium	0.00	-
Actinobacteriota	F0332	0.00	0.00 - 0.00
Actinobacteriota	Varibaculum	0.00	-
Actinobacteriota	Alloscardovia	0.00	-
Actinobacteriota	Bifidobacterium	0.86 ↑	0.04 - 0.76
Actinobacteriota	Gardnerella	0.00	0.00 - 0.00
Actinobacteriota	Corynebacterium	0.00	0.00 - 0.00
Actinobacteriota	Lawsonella	0.00	0.00 - 0.00
Actinobacteriota	Rhodococcus	0.00	-
Actinobacteriota	Rothia	0.00	0.00 - 0.00
Actinobacteriota	Cutibacterium	0.00	0.00 - 0.00
Actinobacteriota	Atopobium	0.00	0.00 - 0.00
Actinobacteriota	Coriobacteriaceae UCG-003	0.00	0.00 - 0.00
Actinobacteriota	Libanicoccus	0.00	0.00 - 0.00
Actinobacteriota	Olsenella	0.00	0.00 - 0.00
Actinobacteriota	Collinsella	0.00	0.00 - 0.26
Actinobacteriota	Enorma	0.00	0.00 - 0.00
Actinobacteriota	Adlercreutzia	0.00	0.00 - 0.00
Actinobacteriota	CHKCI002	0.00	0.00 - 0.00
Actinobacteriota	Denitrobacterium	0.00	0.00 - 0.00
Actinobacteriota	Eggerthella	0.00	0.00 - 0.00
Actinobacteriota	Enterorhabdus	0.00	0.00 - 0.00
Actinobacteriota	Gordonibacter	0.00	0.00 - 0.00
Actinobacteriota	Senegalimassilia	0.00	0.00 - 0.02
Actinobacteriota	Slackia	0.00	0.00 - 0.02
Bacteroidota	Bacteroides	22.80	12.44 - 31.36
Bacteroidota	Barnesiella	2.31 ↑	0.16 - 2.08
Bacteroidota	Coprobacter	0.56 ↑	0.00 - 0.28
Bacteroidota	Dysgonomonas	0.00	-
Bacteroidota	Butyricimonas	0.25 ↑	0.00 - 0.24
Bacteroidota	Odoribacter	0.07 ↓	0.12 - 0.44
Bacteroidota	Sanguibacteroides	0.00	0.00 - 0.00
Bacteroidota	CAG-873	0.00	0.00 - 0.00
Bacteroidota	Muribaculum	0.00	0.00 - 0.00

Name

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Bacteria list

Phylum	Genus	Abundance (%)	Reference (%)
Bacteroidota	Porphyromonas	0.00	0.00 - 0.00
Bacteroidota	Alloprevotella	0.00	0.00 - 0.00
Bacteroidota	Paraprevotella	0.00	0.00 - 0.28
Bacteroidota	Prevotella	0.06	0.00 - 10.44
Bacteroidota	Prevotellaceae Ga6A1 group	0.00	0.00 - 0.00
Bacteroidota	Prevotellaceae NK3B31 group	0.00	0.00 - 0.00
Bacteroidota	Prevotellaceae UCG-001	0.00	0.00 - 0.00
Bacteroidota	Alistipes	3.10	1.56 - 5.46
Bacteroidota	Rikenella	0.00	0.00 - 0.00
Bacteroidota	Rikenellaceae RC9 gut group	0.00	0.00 - 0.00
Bacteroidota	Parabacteroides	6.88 ↑	1.02 - 3.48
Bacteroidota	Hydrothalea	0.00	0.00 - 0.00
Campilobacterota	Arcobacter	0.00	-
Campilobacterota	Campylobacter	0.00	0.00 - 0.00
Cyanobacteria	Arthrospira PCC-7345	0.00	0.00 - 0.00
Desulfobacterota	Bilophila	0.11	0.02 - 0.36
Desulfobacterota	Desulfovibrio	0.00	0.00 - 0.14
Desulfobacterota	Mailhella	0.00	0.00 - 0.00
Elusimicrobiota	Elusimicrobium	0.00	0.00 - 0.00
Firmicutes	Anaeroplasma	0.00	0.00 - 0.00
Firmicutes	Bacillus	0.00	0.00 - 0.00
Firmicutes	Asteroleplasma	0.00	0.00 - 0.00
Firmicutes	Candidatus Stoquefichus	0.00	0.00 - 0.00
Firmicutes	Catenibacterium	0.00	0.00 - 0.00
Firmicutes	Coprobacillus	0.00	0.00 - 0.00
Firmicutes	Erysipelatoclostridium	0.06	0.00 - 0.06
Firmicutes	Erysipelotrichaceae UCG-003	0.15	0.02 - 0.36
Firmicutes	UCG-004	0.00	0.00 - 0.00
Firmicutes	Dielma	0.00	0.00 - 0.00
Firmicutes	Faecalicoccus	0.00	0.00 - 0.00
Firmicutes	Faecalitalea	0.00	0.00 - 0.00
Firmicutes	Holdemanella	0.00	0.00 - 0.06
Firmicutes	Holdemania	0.02	0.00 - 0.06
Firmicutes	Merdibacter	0.00	0.00 - 0.02
Firmicutes	Solobacterium	0.00	0.00 - 0.00
Firmicutes	Turicibacter	0.00	0.00 - 0.06
Firmicutes	[Clostridium] innocuum group	0.00	0.00 - 0.00
Firmicutes	Abiotrophia	0.00	0.00 - 0.00
Firmicutes	Granulicatella	0.00	-
Firmicutes	Marinilactibacillus	0.00	-

Name

Rod Warwick

Cancer type

Melanoma

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18 February 1951

Doctor

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Report from

10 December 2021

Bacteria list

Phylum	Genus	Abundance (%)	Reference (%)
Firmicutes	Enterococcus	0.00	0.00 - 0.00
Firmicutes	Lactobacillus	0.00	0.00 - 0.00
Firmicutes	Leuconostoc	0.01 ↑	0.00 - 0.00
Firmicutes	Weissella	0.00	0.00 - 0.00
Firmicutes	Lactococcus	0.00	0.00 - 0.00
Firmicutes	Streptococcus	0.05	0.02 - 0.24
Firmicutes	Gemella	0.00	0.00 - 0.00
Firmicutes	Staphylococcus	0.00	0.00 - 0.00
Firmicutes	Caldicoprobacter	0.00	0.00 - 0.00
Firmicutes	Catabacter	0.00	0.00 - 0.00
Firmicutes	Christensenella	0.01 ↑	0.00 - 0.00
Firmicutes	Christensenellaceae R-7 group	0.96	0.04 - 1.60
Firmicutes	Clostridium sensu stricto 1	0.12 ↑	0.00 - 0.06
Firmicutes	Anaerofustis	0.00	0.00 - 0.00
Firmicutes	Eubacterium	0.00	0.00 - 0.00
Firmicutes	Defluviitaleaceae UCG-011	0.03 ↑	0.00 - 0.02
Firmicutes	Acetitomaculum	0.00	0.00 - 0.00
Firmicutes	Agathobacter	0.00	0.00 - 0.00
Firmicutes	Anaerosporebacter	0.00	0.00 - 0.00
Firmicutes	Anaerostignum	0.00	0.00 - 0.00
Firmicutes	Anaerostipes	0.04	0.02 - 0.30
Firmicutes	Blautia	0.00	0.00 - 0.12
Firmicutes	Butyrivibrio	0.00	0.00 - 0.00
Firmicutes	CAG-56	0.00	0.00 - 0.00
Firmicutes	CHKCI001	0.00	0.00 - 0.00
Firmicutes	Catenibacillus	0.00	0.00 - 0.00
Firmicutes	Cellulosilyticum	0.00	0.00 - 0.00
Firmicutes	Coprococcus	0.33	0.06 - 1.70
Firmicutes	Eisenbergiella	0.05 ↑	0.00 - 0.00
Firmicutes	Epulopiscium	0.00	0.00 - 0.00
Firmicutes	Frisingicoccus	0.00	0.00 - 0.00
Firmicutes	Fusicatenibacter	0.00	-
Firmicutes	GCA-900066575	0.06	0.00 - 0.08
Firmicutes	GCA-900066755	0.00	0.00 - 0.00
Firmicutes	Howardella	0.00	0.00 - 0.00
Firmicutes	Hungatella	0.02 ↑	0.00 - 0.00
Firmicutes	Johnsonella	0.00	0.00 - 0.00
Firmicutes	Lachnoanaerobaculum	0.00	0.00 - 0.00
Firmicutes	Lachnoclostridium	0.24	0.14 - 0.70
Firmicutes	Lachnospira	2.79 ↑	0.00 - 1.90

Name

Rod Warwick

Cancer type

Melanoma

Date of birth

18 February 1951

Doctor

Dr. Jordan Bradford

Report from

10 December 2021

Bacteria list

Phylum	Genus	Abundance (%)	Reference (%)
Firmicutes	Lachnospiraceae FCS020 group	0.03	0.02 - 0.30
Firmicutes	Lachnospiraceae FE2018 group	0.00	0.00 - 0.00
Firmicutes	Lachnospiraceae NC2004 group	0.32	0.00 - 0.36
Firmicutes	Lachnospiraceae ND3007 group	2.22	0.20 - 2.32
Firmicutes	Lachnospiraceae NK4A136 group	0.35 ↑	0.00 - 0.00
Firmicutes	Lachnospiraceae NK4B4 group	0.00	0.00 - 0.00
Firmicutes	Lachnospiraceae UCG-001	0.17	0.00 - 0.44
Firmicutes	Lachnospiraceae UCG-003	0.00	0.00 - 0.00
Firmicutes	Lachnospiraceae UCG-004	0.00	0.00 - 0.30
Firmicutes	Lachnospiraceae UCG-007	0.00	0.00 - 0.00
Firmicutes	Lachnospiraceae UCG-008	0.00	0.00 - 0.02
Firmicutes	Lachnospiraceae UCG-010	0.28 ↑	0.02 - 0.24
Firmicutes	Marvinbryantia	0.00	0.00 - 0.00
Firmicutes	Moryella	0.00	0.00 - 0.04
Firmicutes	Murimonas	0.00	0.00 - 0.00
Firmicutes	Oribacterium	0.00	0.00 - 0.00
Firmicutes	Roseburia	0.00	0.00 - 0.14
Firmicutes	Sellimonas	0.00	0.00 - 0.00
Firmicutes	Shuttleworthia	0.00	0.00 - 0.00
Firmicutes	Stomatobaculum	0.00	0.00 - 0.00
Firmicutes	Tuzzerella	0.00	0.00 - 0.00
Firmicutes	Tyzzera	0.00	0.00 - 0.06
Firmicutes	[Bacteroides] pectinophilus group	0.00	0.00 - 0.00
Firmicutes	[Eubacterium] eligens group	0.77	0.18 - 2.54
Firmicutes	[Eubacterium] fissicatena group	0.00	0.00 - 0.00
Firmicutes	[Eubacterium] hallii group	0.30 ↑	0.00 - 0.08
Firmicutes	[Eubacterium] oxidoreducens group	0.00	0.00 - 0.02
Firmicutes	[Eubacterium] ruminantium group	0.00	0.00 - 0.16
Firmicutes	[Eubacterium] ventriosum group	0.06	0.00 - 0.14
Firmicutes	[Eubacterium] xylanophilum group	0.31	0.00 - 0.34
Firmicutes	[Ruminococcus] gauvreauii group	0.00	0.00 - 0.00
Firmicutes	[Ruminococcus] torques group	0.00	0.00 - 0.00
Firmicutes	Monoglobus	0.52 ↑	0.06 - 0.38
Firmicutes	Butyricoccus	0.43	0.10 - 0.48
Firmicutes	UCG-008	0.00	0.00 - 0.00
Firmicutes	UCG-009	0.00	0.00 - 0.00
Firmicutes	Acetanaerobacterium	0.00	0.00 - 0.00
Firmicutes	Colidextribacter	0.05	0.02 - 0.18
Firmicutes	Flavonifractor	0.02	0.00 - 0.06
Firmicutes	Intestinimonas	0.19 ↑	0.00 - 0.06

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Bacteria list

Phylum	Genus	Abundance (%)	Reference (%)
Firmicutes	NK4A214 group	0.22	0.00 - 0.86
Firmicutes	Oscillibacter	1.10 ↑	0.00 - 0.08
Firmicutes	Oscillospira	0.06	0.00 - 0.10
Firmicutes	Papillibacter	0.00	0.00 - 0.00
Firmicutes	Pseudoflavonifractor	0.00	0.00 - 0.00
Firmicutes	UCG-002	0.15	0.02 - 0.56
Firmicutes	UCG-003	0.22 ↑	0.00 - 0.12
Firmicutes	UCG-005	0.00	0.00 - 0.34
Firmicutes	V9D2013 group	0.00	0.00 - 0.00
Firmicutes	Anaerofilum	0.00	0.00 - 0.00
Firmicutes	Anaerotruncus	0.03 ↑	0.00 - 0.00
Firmicutes	Angelakisella	0.00	0.00 - 0.00
Firmicutes	CAG-352	0.00	0.00 - 0.00
Firmicutes	Candidatus Soleaferrea	0.00	0.00 - 0.00
Firmicutes	DTU089	0.12 ↑	0.00 - 0.02
Firmicutes	Faecalibacterium	3.94 ↓	4.44 - 12.86
Firmicutes	Fournierella	0.00	0.00 - 0.00
Firmicutes	Harryflintia	0.00	0.00 - 0.00
Firmicutes	Negativibacillus	0.00	0.00 - 0.08
Firmicutes	Paludicola	0.00	0.00 - 0.00
Firmicutes	Phoceia	0.00	0.00 - 0.00
Firmicutes	Pygmaibacter	0.00	0.00 - 0.00
Firmicutes	Ruminococcus	1.70 ↑	0.12 - 1.60
Firmicutes	Subdoligranulum	0.62	0.20 - 2.20
Firmicutes	UBA1819	0.04	0.00 - 0.04
Firmicutes	[Eubacterium] siraeum group	6.35 ↑	0.00 - 1.40
Firmicutes	Hydrogenoanaerobacterium	0.00	0.00 - 0.00
Firmicutes	Peptococcus	0.02	0.00 - 0.04
Firmicutes	Family XIII AD3011 group	0.03	0.00 - 0.06
Firmicutes	Family XIII UCG-001	0.01	0.00 - 0.04
Firmicutes	S5-A14a	0.00	0.00 - 0.00
Firmicutes	[Eubacterium] brachy group	0.00	0.00 - 0.00
Firmicutes	[Eubacterium] nodatum group	0.01 ↑	0.00 - 0.00
Firmicutes	Intestinibacter	0.02 ↑	0.00 - 0.00
Firmicutes	Peptoclostridium	0.00	0.00 - 0.00
Firmicutes	Peptostreptococcus	0.00	0.00 - 0.00
Firmicutes	Romboutsia	0.00	0.00 - 0.00
Firmicutes	Terrisporobacter	0.00	0.00 - 0.00
Firmicutes	Sedimentibacter	0.00	-
Firmicutes	Anaerococcus	0.00	0.00 - 0.00

Name

Rod Warwick

Cancer type

Melanoma

Date of birth

18 February 1951

Doctor

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10 December 2021

Bacteria list

Phylum	Genus	Abundance (%)	Reference (%)
Firmicutes	Ezakiella	0.00	0.00 - 0.00
Firmicutes	Fenollaria	0.00	0.00 - 0.00
Firmicutes	Finegoldia	0.00	0.00 - 0.00
Firmicutes	Murdochiella	0.00	0.00 - 0.00
Firmicutes	Parvimonas	0.00	0.00 - 0.00
Firmicutes	Peptoniphilus	0.00	0.00 - 0.00
Firmicutes	Fastidiosipila	0.00	0.00 - 0.00
Firmicutes	Ruminiclostridium	0.00	0.00 - 0.00
Firmicutes	Desulfitibacter	0.00	-
Firmicutes	Acidaminococcus	0.00	0.00 - 0.00
Firmicutes	Phascolarctobacterium	1.53	0.00 - 1.84
Firmicutes	Succiniclasticum	0.00	0.00 - 0.00
Firmicutes	Megamonas	0.00	0.00 - 0.00
Firmicutes	Mitsuokella	0.00	0.00 - 0.00
Firmicutes	Allisonella	0.00	0.00 - 0.00
Firmicutes	Anaeroglobus	0.00	0.00 - 0.00
Firmicutes	Dialister	0.05	0.00 - 2.60
Firmicutes	Megasphaera	0.00	0.00 - 0.00
Firmicutes	Negativicoccus	0.00	0.00 - 0.00
Firmicutes	Veillonella	0.14 ↑	0.00 - 0.10
Fusobacteriota	Fusobacterium	0.00	0.00 - 0.00
Fusobacteriota	Leptotrichia	0.00	0.00 - 0.00
Fusobacteriota	Sneathia	0.00	0.00 - 0.00
Patescibacteria	Candidatus Saccharimonas	0.00	0.00 - 0.00
Patescibacteria	TM7x	0.01	0.00 - 0.02
Proteobacteria	Brevundimonas	0.00	0.00 - 0.00
Proteobacteria	PMMR1	0.00	0.00 - 0.00
Proteobacteria	Bosea	0.00	-
Proteobacteria	Rhodobacter	0.00	-
Proteobacteria	Sphingobium	0.00	0.00 - 0.00
Proteobacteria	Sphingomonas	0.00	0.00 - 0.00
Proteobacteria	Succinatimonas	0.00	0.00 - 0.00
Proteobacteria	Succinivibrio	0.00	0.00 - 0.00
Proteobacteria	Lautropia	0.00	-
Proteobacteria	Comamonas	0.00	0.00 - 0.00
Proteobacteria	Neisseria	0.00	0.00 - 0.00
Proteobacteria	Oxalobacter	0.00	0.00 - 0.00
Proteobacteria	Parasutterella	0.86	0.00 - 0.96
Proteobacteria	Sutterella	0.05	0.02 - 2.96
Proteobacteria	Escherichia-Shigella	0.00	0.00 - 0.00

Name

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Bacteria list

Phylum	Genus	Abundance (%)	Reference (%)
Proteobacteria	Hafnia-Obesumbacterium	0.00	-
Proteobacteria	Actinobacillus	0.00	0.00 - 0.00
Proteobacteria	Aggregatibacter	0.00	0.00 - 0.00
Proteobacteria	Haemophilus	0.00	0.00 - 0.14
Proteobacteria	Acinetobacter	0.00	0.00 - 0.00
Proteobacteria	Pseudomonas	0.00	0.00 - 0.00
Proteobacteria	Stenotrophomonas	0.00	0.00 - 0.00
Synergistota	Cloacibacillus	0.00	0.00 - 0.00
Synergistota	Pyramidobacter	0.00	0.00 - 0.00
Synergistota	Synergistes	0.00	0.00 - 0.00
Verrucomicrobiota	Victivallis	0.48 ↑	0.00 - 0.20
Verrucomicrobiota	Akkermansia	1.19	0.00 - 2.32
Incertae Sedis_3	Blastocystis	0.00	0.00 - 0.00

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About BiomeOne®

CE BiomeOne® was developed by the company Biome Diagnostics GmbH. Biome Diagnostics GmbH is dual ISO certified (ISO 9001:2015 and ISO 13485:2016).

BiomeOne and its parameter "clinical response" fulfils the requirements of the European Directive 98/79 EC for in vitro diagnostic medical devices and is registered as a CE-IVD product by Biome Diagnostics GmbH, Alleestraße 90, 2103 Langenzersdorf, Austria. The parameter "tolerability" is Research-Use-Only (RUO).

The parameters diversity, bacterial richness, and enterotype are scientifically established and serve to improve the overall assessment of the intestinal microbiome of a patient.

The entire analysis can be used for both clinical and scientific purposes.

Intended use

BiomeOne is a cloud-based in vitro diagnostic software intended for the detection of responders and non-responders to checkpoint inhibitor based cancer immunotherapy (CTLA-4, PD-1, PD-L1) based on stool microbiome profiles of late-stage cancer patients. The product encompasses the proprietary biomarker for response prediction and the platform service provided to healthcare professionals to order the kit and analysis, and download the analysis report. The cloud-based nature of the software is able to store, transfer and analyse FASTQ files from next-generation-sequencing platforms and generate a PDF report containing the predicted response information. The diagnostic software performs bioinformatic workflows and infers response to checkpoint inhibitor based cancer immunotherapy using a proprietary biomarker signature based on statistical algorithms of microbiome samples from patients with non-small cell lung cancer, renal cell carcinoma and malignant melanoma.

The results described in the BiomeOne report are intended as additional information for the treating physician and should not be used as the sole basis for any treatment decision. BiomeOne should only be used by qualified healthcare professionals. It provides clinically relevant and reproducible, quantitative data for improving therapy management.

The primary performance study was conducted in the following three tumour types: non-small cell lung cancer, renal cell carcinoma, and malignant melanoma. Female and male participants were included in the study to equal parts. BiomeOne is

indicated for in-vitro diagnostic use with a response prediction sensitivity of > 80%.

Intended patient groups

BiomeOne has been developed for use in stage III and stage IV cancer patients and validated in the following indications: non-small cell lung cancer, renal cell carcinoma and malignant melanoma. The analysis can be used in patients between 18 and 90 years of age.

Diagnostic significance

BiomeOne identifies patients who will benefit (responder) or will not benefit (non-responder) from a treatment with checkpoint inhibitor based cancer immunotherapy (CTLA-4, anti-PD-1 or anti-PD-L1). Responders are defined as patients with either complete response (CR) or partial response (PR). Non-responders are defined as patients with stable disease (SD) or progressive disease (PD).

Laboratory analysis

BiomeOne analysis uses microbial DNA, which is obtained from stool samples of cancer patients. The samples are collected by the patients themselves. CE-IVD labeled stool tubes from Norgen® Biotek are used for temporary storage and transportation of the stool samples. In the laboratory, 50 - 1000 ng of a microbiome sample from a patient is subjected to 16S rRNA library construction. This is followed by amplicon sequencing with an average of 460 base pairs. Subsequently, clustering is carried out at species level.

Using the Illumina MiSeq® platform, libraries are sequenced at high uniform depth (> 50,000 paired-end reads).

Bioinformatic analysis

A proprietary analysis pipeline assesses the raw data from DNA sequencing and enables the identification of cancer patients who are likely (Sensitivity > 80%) to benefit from a checkpoint inhibitor based cancer immunotherapy (CTLA-4, anti-PD-1 or anti-PD-L1). The mathematical models for calculating the clinical response are based on a random forest model. In addition, sequencing data are analyzed for irAEs of any grade during a checkpoint inhibitor as well as for specific signatures including bacterial constellations and parameters such as diversity and bacterial richness.

Limitations

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About BiomeOne®

It is advised to wait at least 30 days after the last administration of systemic antibiotics before collecting a stool sample. The detrimental effects of antibiotics on the intestinal microbiome can significantly impact the test results.

Legal clarification

Biome Diagnostics makes no promises or guarantees that any patient will respond or not respond to a particular treatment. Additionally, Biome Diagnostics makes no promises or guarantees for the potential occurring or non-occurring of immune related adverse events.

Biome Diagnostics makes no promises or guarantees that a healthcare provider, insurer or other third payor, private or governmental, will reimburse a patient for the costs of BiomeOne.

The information in this report must be considered with all other relevant information about the patient before a treatment decision is made. Decisions about patient care and treatment must be based on the independent medical judgment of the treating physician.

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References

Clinical response

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