

CE IVD

MICROBIOTA

Solution A / Solution B

Rev. 01/2022

MICROBIOTA SOLUTION A/B

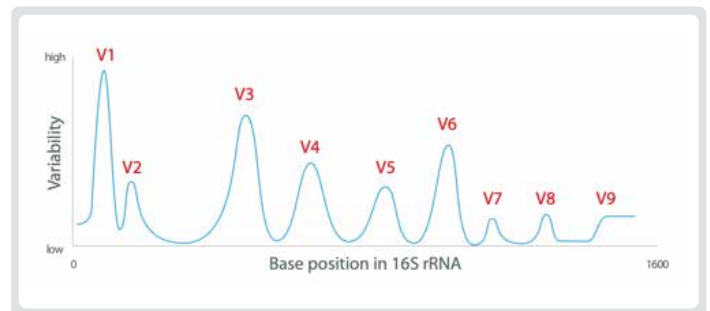
Clinical Relevance

The composition of the bacterial flora, the microbiota, is important in multiple physiological processes and is notoriously related to the efficiency of the immune system and protection against pathogens. It is now known how alterations in the bacterial population are associated with pathological conditions. The majority of these microorganisms are part of the gut microbiota, but also other microbial communities like vaginal, skin or respiratory predispose to health and disease. It is now known that alterations in the bacterial population are associated with pathological conditions. But many of these microbial species couldn't be detected by common culture-dependent methods. Having a standardized test for the analysis of the microbiome in the clinical setting can help in the identification of bacterial profiles already associated with specific pathologies and is useful in identifying new bacterial profiles. The use of a standardized diagnostic test can facilitate the study of corrective therapies.

Intended Use

The Microbiota Solution A/B kit is an *in vitro* device based on the amplification of nucleic acids by PCR ("Polymerase Chain Reaction") of the hypervariable regions of the bacterial 16S rDNA gene, for the qualitative evaluation of the human intestinal microbiota and other biological samples (e.g. vaginal swab, endometrial catheter, sputum, skin swab), starting from a bacterial genomic DNA sample, followed by Sequencing in Next Generation Sequencing (NGS).

16S rDNA gene – Target for the bacterial identification



Microbiota Solution A – V1- V2-V3 hypervariable regions

Microbiota Solution B – V3- V4-V6 hypervariable regions

Sample Type

AD4SEQ Microbiota Solution A (AD-001.024)	<ul style="list-style-type: none"> ✓ Stool ✓ Skin Sample ✓ Sputum ✓ Saliva
AD4SEQ Microbiota Solution B (AD-002.024)	<ul style="list-style-type: none"> ✓ Stool ✓ Rectal Swab ✓ Vaginal Swab ✓ Endometrial Catheter

NGS Instruments

- ✓ Illumina® MiSeq™

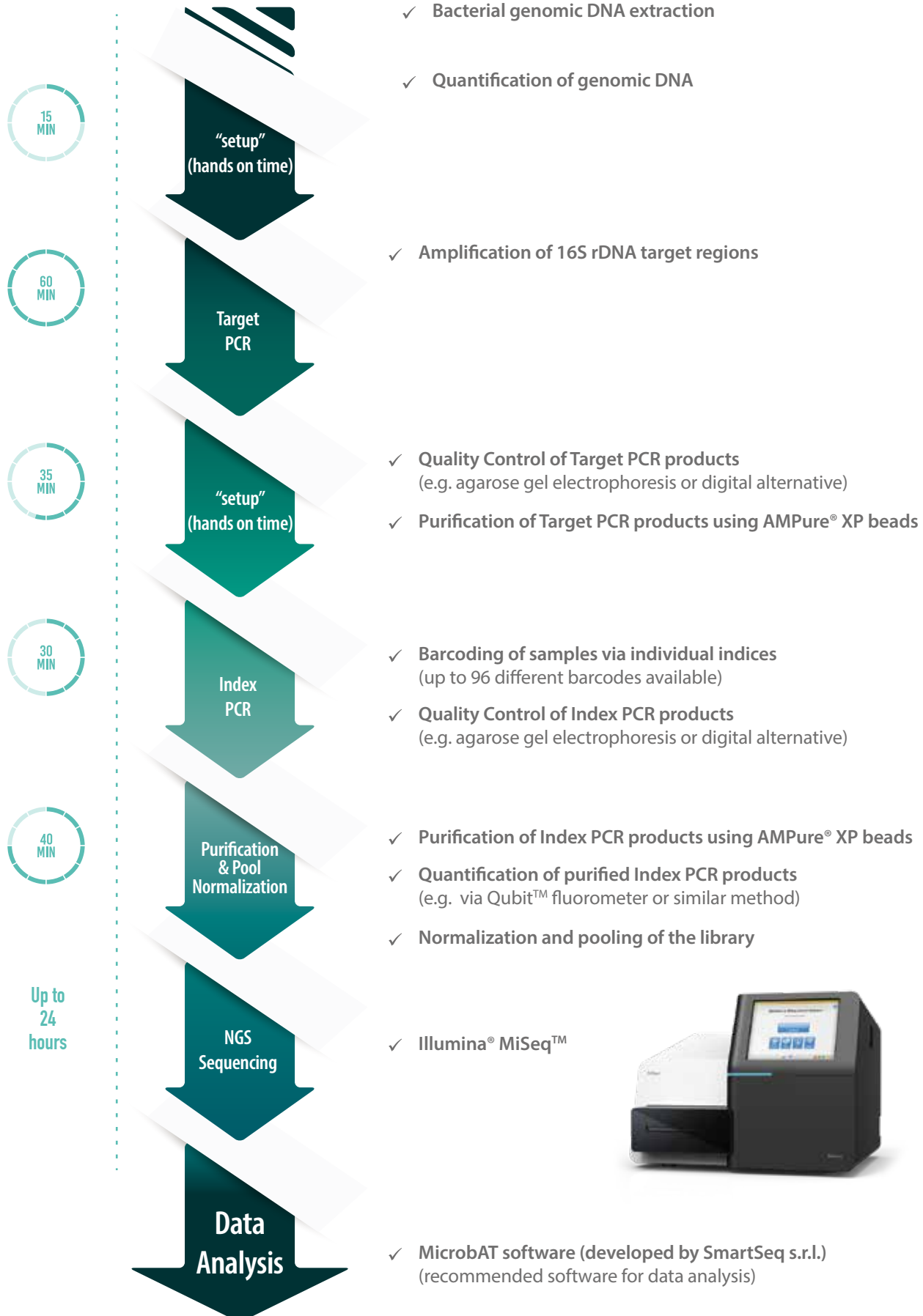
Performance Features

- ✓ Library preparation within 8 hours
- ✓ DNA input: 5ng
- ✓ Data analysis can be performed with dedicated software (developed by SmartSeq S.r.l.)

DNA Extraction – Validated Methods

- ✓ QIAamp® PowerFecal® Pro DNA Kit (Qiagen)
- ✓ QIAamp® Fast DNA Stool Mini Kit (Qiagen)
- ✓ QIAamp® DNA Microbiome Kit (Qiagen)
- ✓ Any other extraction method available in the laboratory can be used after validation.

Workflow Overview



We recommend evaluating any data obtained by always referring to a patient's clinical history and other diagnostic information available to best interpret the results of the microbial profile.

Performance Features

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- ✓ DNA input: 5ng
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Sequencing Information

illumina® Kit	Number of samples	Sequencing time (illumina® Official Data)
MiSeq™ Reagent Nano Kit v2 (500 cycles) - cod: MS-103-1003	12	~ 28 h
MiSeq™ Reagent Kit v2 (500 cycles) - cod: MS-102-2003	96	~ 39 h

Ordering Information

			Cat. No.
AD4SEQ	Microbiota Solution A	24 rxns	AD-001.024
AD4SEQ	Microbiota Solution B	24 rxns	AD-002.024