

# [EN] Instructions for use

## SAMPLING.pro

**Version:** 1.0

**REF:** 4600

**GTIN:** 4260582940019

**e-IFU Online:** [www.biomes.world/ivd/samplingpro](http://www.biomes.world/ivd/samplingpro)



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### Intended Purpose

Intended for collecting and stabilizing unprocessed stool samples for DNA-based molecular laboratory examination. The device is designed for health subjects to non-invasively collect stool samples with an applicator (swap) at home and to analyze the samples' DNA content in a laboratory environment by trained healthcare professionals.

The device contains a specimen receptacle prefilled with stabilizing reagent to maintain the molecular integrity of the sample DNA content and silica beads to assist sample distribution in the reagent. The device is designed for single use sample collection without generating a test result.

### General Device Description

SAMPLING.pro provides a reliable and easy-to-use process for collecting, preserving, and preparing stool samples for subsequent laboratory analysis, ensuring the accuracy and reliability of molecular testing.

### SAMPLING.pro

- can be used with self-validated molecular diagnostic applications which may include DNA-extraction, 16S rRNA gene microbiome profiling, shotgun sequencing and polymerase chain reaction.
- is made for ease of use: Clean sampling with specimen applicators such as swabs but without the need to process the sample for analysis
- contains uniquely 2D matrix-coded specimen receptacle to ensure sample traceability in the testing laboratories.
- contains a DNA stabilizing reagent to ship fecal samples at ambient temperature safely
- is intended for professional use only (e.g. testing provider)

### Content

Each SAMPLING.pro contains

- 1x sample tube as container with 0.75 mL stabilizing reagent to preserve the molecular integrity of the DNA content within the stool sample, and silica beads to facilitate even distribution of the stool sample within the stabilizing reagent to reduce sample heterogeneity. The beads maximize the exposure of the sample to the reagent, enhancing the preservation of DNA integrity.
- 1x sampling applicator to collect stool samples safely and effectively in a home environment.
- 1x instructions for use and safety datasheet (PDF-Download, print version on request).

### Storage

SAMPLING.pro can be stored between 8 – 30 °C to maintain integrity for up to 24 months without any performance reduction. Take care of the expiry date on the label. No quality guarantee can be given after the expiry date has been reached. SAMPLING.pro must NOT be stored at 2-8 °C until use.

### No additionally required reagents or accessories

## Precautions

To use SAMPLING.pro safely, it is essential to strictly follow the instructions for use. SAMPLING.pro does not contain components in quantities that pose a health risk to the user in case of accidental contact.

## Warnings



- For external use only.
- Avoid contact with skin and eyes. In case of contact with the stabilizing liquid, rinse thoroughly with water.
- Do not spill the stabilizing liquid in the tube. Do not ingest.
- Keep out of reach of children.
- If there is evidence of damage or visible contamination to the product, the expiration date has passed, the package is open or damaged, or there are other signs of deterioration, do not use SAMPLING.pro
- Stool of all human subjects is considered potentially infectious. All necessary precautions recommended by the appropriate authorities in the country of use should be taken when working with stool.



Further details can be found in the **safety data sheet** available via the QR code.

Serious incidents must be reported to BIOMES NGS GmbH as legal manufacturer and the national supervisory authorities.

## Disposal instructions

Dispose of supplied materials according to local, provincial or federal regulations.

## Stool sample collection and transport

Solid stool samples are taken directly from toilet paper or any supplied material (e.g. Feces Catcher) using the supplied sterile swab and transferred into the SAMPLING.pro receptacle. **Limitation:** SAMPLING.pro is not intended for sampling liquid stool.



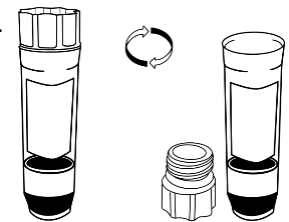
*Before use, please check if the packaging or if the receptacle is visibly damaged or has leaked, and if the required accessories (swab) are available. Otherwise contact customer support of your test provider.*

### Step 1:

Tear open the SAMPLING.pro paper bag at the pull tab (notch). Remove the sterile packed sampling swab and the sample tube to place it on clean and dry surface.

### Step 2:

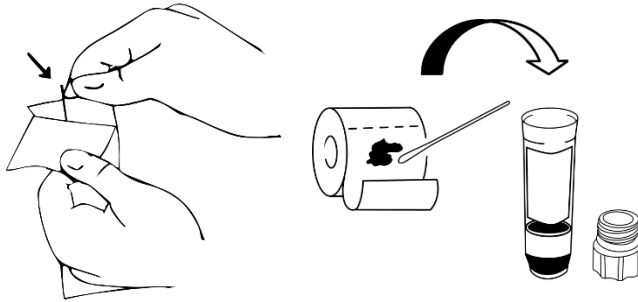
Unscrew the lid of the sample tube counterclockwise. Set the cap aside (with the top facing down) for later use.



*Do not spill the liquid. Do not fill the container with water.*

**Step 3:**

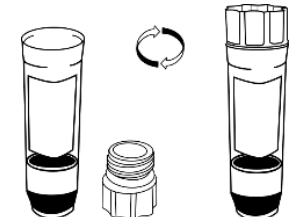
Peel-open the pouch of the sterile swab and remove it from the packaging without touching the tip. Take the swab and collect a small amount of stool (rice grain) by wiping it off from toilet paper or any supplied material (e.g. Feces Catcher).



*Do not spill any liquid due to excessive sample input. Not all sample particles will fully homogenize. The sample must be completely covered with the transport reagent to ensure sample stability.*

**Step 5:**

Replace the receptacle cap from step 2. Securely fasten the lid onto the sample tube by twisting it in a clockwise direction until the tube is tightly closed.



**Sample storage and transport**

Send the sample for processing following the delivery instructions supplied separately by the test provider. For best performance ship the sample within 3 days to the test provider for professional analysis.



*The collected stool sample is stable at 8 – 30 °C during transport. Transport at -20 °C is not recommended as the freezing and thawing process can compromise the integrity of the DNA. If the stool sample cannot be shipped within 3 days after sampling, store the sample at 4 to 8 °C until shipment.*

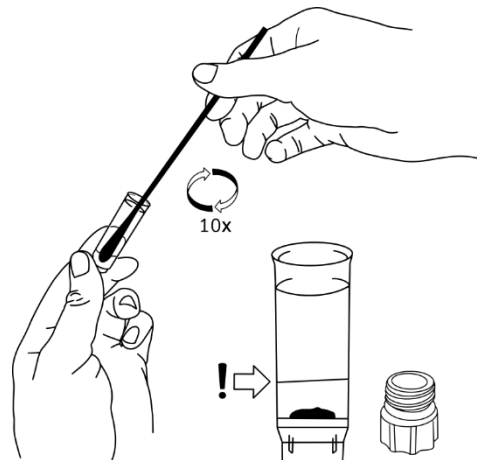


*Collect fecal sample free of urine or toilet water.*

**Step 4:**

While holding the open sample tube securely in one hand, gently insert the tip of the swab containing the stool sample into the sample receptacle, ensuring that it is fully covered with liquid.

To transfer the sample into the stabilization liquid, rotate the swab quickly up to 10 times between your thumb and forefinger. Place and dispose the swab in original packaging.












SAMPLING.pro is designed as primary container to transport stool specimen to a laboratory as “exempt human specimen” according to packaging instruction P650 (applies to UN3373 category B) of International Carriage of Dangerous Goods by Road (ADR) and the International Air Transport Association (IATA). The shipping accessories (secondary and tertiary packaging) are not provided by SAMPLING.pro.

### Disclaimer

The test provider must validate the in-house performance of the device before routine laboratory use. The device can be used for *in vitro diagnostic* assays. It is the sole responsibility of the professional user (laboratory) to validate the device performance in combination with a particular downstream *in vitro* diagnostic DNA assay and / or automation device.

### Symbol legend

Description	Symbol	Description	Symbol
Reference Number		Manufacturer	
LOT-Number		Instructions For Use	
Expiry Date YYYY		Single Use Only	
Temperature range (°C)		<i>In-Vitro-Diagnostic</i> Device	
Unique Product Identifier			

### Technical Support

Contact BIOMES NGS GmbH Support: [info@biomes.world](mailto:info@biomes.world)

### Version control

Rev-no.	Description of Change	Date
0	IFU creation according to IVDR	01.08.2024
1		