

MetaXplore™ GI Plus Sampling Instructions

Unlock health from within

Stool Sample Collection Kit

REF MTXC-2403

MetaXplore™
Powered by MiCROBA

**Congratulations on taking
the first step towards
exploring your digestive and
gut microbiome health to
unlock health from within.**

To help your healthcare professional capture meaningful insights from your sample, please read the instructions in full before taking your sample and follow the directions for use.

Scan this QR code for a
visual guide to the manual.
For more information,
contact the Invivo Customer
Service team at **0333 241 2997**



What to know two weeks ahead of taking your sample

When to collect and return your sample

Only collect your sample on a **Monday, Tuesday, or Wednesday**. Return it to your local post office **before 1pm on the same day.***

Continue your usual routine

Keep your regular exercise, diet, and medications unless instructed differently by your healthcare provider.

What kind of sample to provide

Take the sample from a **normal bowel movement** that reflects how things usually are for you.

If you menstruate

Avoid collecting your sample during your period or within three days afterward.

If you're on medication

Please note that antibiotics, antimicrobials and other medications can impact test results. Please refer to our FAQs at the back of this booklet for more information, or consult your healthcare provider.

*Post office express post packages cut-off time



48 hour preparation

When receiving kit



- Before using the kit, check that it is addressed to you. Avoid using someone else's kit or swapping items, as everything inside is matched to your personal details.
- Unpack your kit and check you have all the components.
- Read and understand all instructions.
- Freeze your ice brick for sample return in the box.

Two days before taking your sample



- Avoid drinking alcohol.
- If possible, avoid taking NSAIDs (e.g. ibuprofen, aspirin) unless directed by a healthcare professional.



24 hour preparation

One day before taking your sample

- Be ready to take your sample from your first bowel movement of the day.
- For those who menstruate, avoid collecting during or three days after menstruation.

Day of sample

- Collect and label samples **ONLY ON MONDAY, TUESDAY OR WEDNESDAY** and return them **before 1pm on the same day**.
- Allow 30 minutes to complete the sampling process.
- Ensure you have read and understood all instructions. If you need help, call Customer Services at **0333 241 2997**.



Make sure you have all of the below items included in your Co-Biome™ MetaXplore™ GI Plus sampling kit

The below items are included in your sampling kit:



1 Instruction booklet



2 Checklist



3 Collection paper



4 Device 1



5 Device 2



6 Device 3



7 Ice brick



Before starting your test, ensure the kit is addressed to you and contains all listed items. If anything is missing or damaged, contact the Invivo Customer Service team by email cegsupport@invivo.odoo.com or phone **0333 241 2997**.



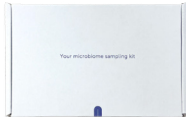
8 Collection stickers x 2



9 Pouch A



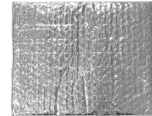
10 Pouch B



11 Kit box



12 Pre-paid envelope



13 Thermal pouch

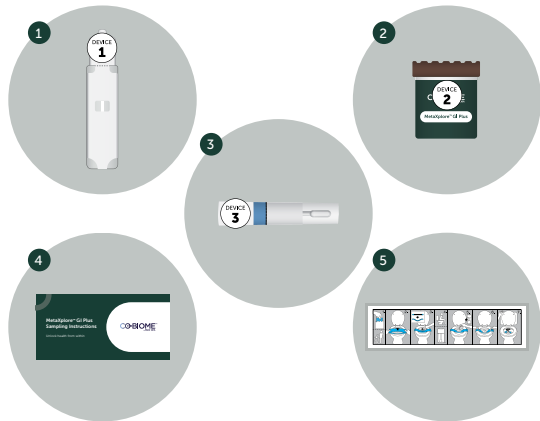


STEP 1

Prepare kit items to take your sample

When you are ready to collect a sample, take the collection kit to the toilet. You will need:

1. Device 1
2. Device 2
3. Device 3
4. Instruction booklet
5. Collection paper

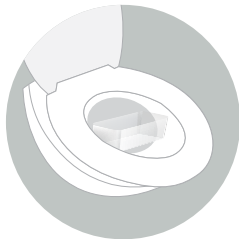
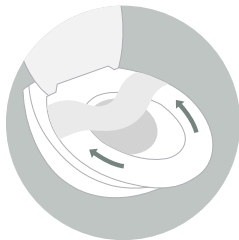


STEP 2

Prepare the collection paper on the toilet

Open and unfold the collection paper provided and slip it over the toilet seat.

Alternatively, you may line a clean disposable container with the collection tissue and place the container into the toilet bowl after urination. This collection method is recommended if you have loose bowel movements.



STEP 3

Provide faecal sample onto the collection paper

Ensure your faecal sample remains uncontaminated from urine, toilet water and other contaminants. You may need to urinate before opening the collection paper accessory and starting the faecal collection process.

In case you have a problem with your first collection attempt, use a disposable container lined with toilet paper.



STEP 4

Take note of your stool consistency

Please take note of your stool consistency using the Bristol Stool Chart below as you will need to record this in a later step.



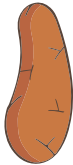
Type 1

Separate hard lumps like nuts (hard to pass)



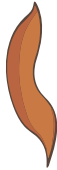
Type 2

Sausage shape but lumpy



Type 3

Like a sausage but with cracks on its surface



Type 4

Like a sausage or snake, smooth and soft



Type 5

Soft blobs with clear-cut edges (passed easily)



Type 6

Fluffy pieces with ragged edges, a mushy stool



Type 7

Watery, no solid pieces; entirely liquid

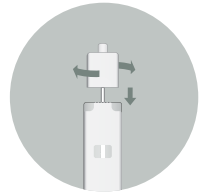
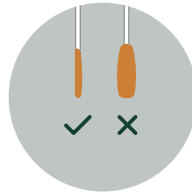
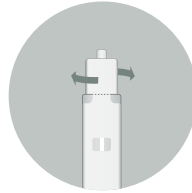


STEP 5

Use Device 1 to collect your capped-vial sample

Write your full legal name, date of birth, and the date of collection on the label using a black or blue pen.

Twist the cap to open the sample bottle. Scrape the stick along the stool until the grooves are covered. You only need a small amount for the test. Please do not add extra. Place the stick back in the bottle and twist until secure. **Do not reopen the bottle after sealing it.**

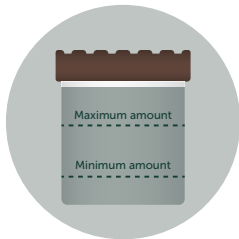


STEP 6

Use Device 2 to collect your pot sample

Open Device 2 and use the scoop inside the pot lid to collect the faecal material. Collect material from three to five different sections of the sample to fill the pot halfway. Ensure there is a minimum collection of one tablespoon and a maximum of $\frac{2}{3}$ of the pot.

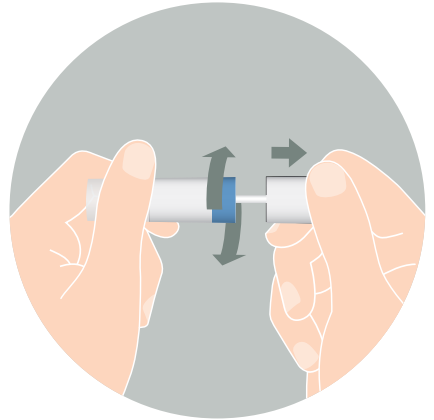
If blood or mucus is present in your stool, please avoid collecting from those areas.



STEP 7

Use Device 3 to collect your swab sample

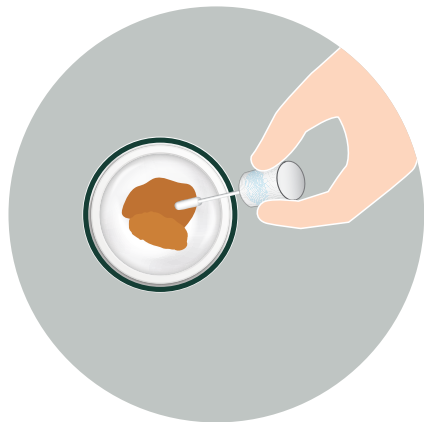
Open Device 3 by twisting and pulling with a firm grip. It is important that the swab tip does not come into contact with your hand or any other surfaces, as this can compromise with the sample.



Take a small amount of the stool from Device 2 using the swab. Only a small smear is needed with no lumps captured on the swab.

Immediately place the swab back in the tube without touching any other surfaces. Firmly close the tube until you hear it click.

Tear the edges of the collection tissue and drop into the toilet to flush.



Lightly touch the round end of the swab to pick up a small smear. It is critical not to overload your sample. Only a small discolouration of the swab is needed for testing.





Overloaded
sample



Underloaded
sample

Do not overload or underload your sample. Our lab may not be able to process your sample or provide a report for your swab if it contains too much or too little faecal material.



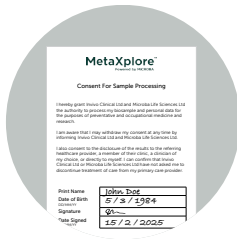
STEP 8

Label your sample and complete your Patient Consent Form

Use the collection stickers provided to label Device 2 and Device 3 with your full legal name, date of birth, time (AM or PM), date of collection and stool type.

To ensure we can process your sample, please complete the patient consent form and return it along with your labelled sample.

We will not be able to process your samples without this information.



STEP 9

Place Device 3 in Pouch A

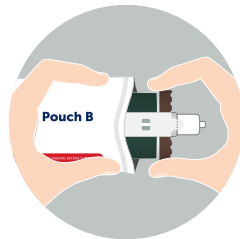
Place Device 3 in Pouch A provided and press the pouch closed to seal.
Do not place Device 3 in the fridge.



STEP 10

Place Device 1 and Device 2 in Pouch B

Place Device 1 and Device 2 in Pouch B provided. **Do not discard the absorbent paper.** Insert and press the pouch closed to seal.

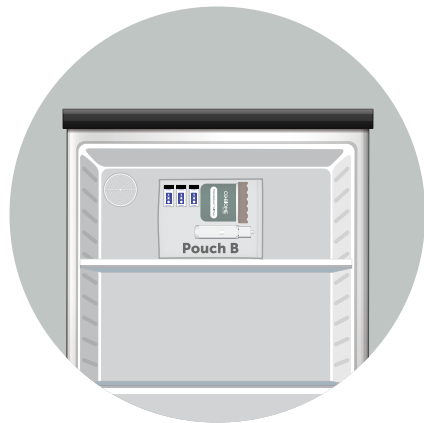


STEP 11

Refrigerate Pouch B for a minimum of 30 minutes

Place **only Pouch B** in the fridge for a minimum of 30 minutes or until ready to post that same day.

Do not place Pouch A in the fridge at any time.

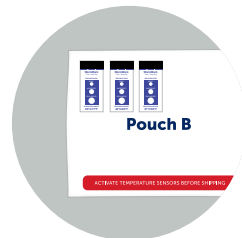
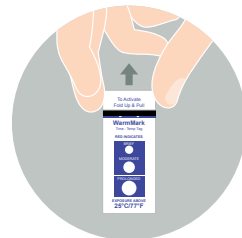


STEP 12

Remove Pouch B from the fridge and activate all temperatures sensors

Remove Pouch B from the fridge when ready to post, ensuring the sample has been refrigerated for **at least 30 minutes**.

Activate the temperature sensors attached to the pouch in a room that is 30°C or below. To activate, fold up and pull the indicator activation tab until the tab and barrier film has been removed.



STEP 13

Pack the samples for return

Pack Pouch B and ice brick into the thermal pouch, then place the thermal pouch inside the kit box (with the insert removed). **Do not include Pouch A in the kit box.**

Place Pouch A directly into the pre-paid envelope. Add the kit box (containing the thermal pouch with Pouch B and ice brick provided) separately into the pre-paid envelope.



STEP 14

Post over the counter at the Post Office

Return to our laboratory by taking to your nearest Post Office and returning **over the counter**.



Frequently Asked Questions

Should I discontinue probiotics or supplements before sampling?

We recommend maintaining your normal supplement and probiotic regime for two weeks prior to sampling, unless you have been advised to discontinue them by your healthcare professional. Always consult with your healthcare professional before making any changes to prescribed probiotics or supplements and do not discontinue any medications without their advice. Please collect a sample from a bowel movement that is typical for you.

Will taking antibiotics and antimicrobial supplements prior to sampling change my results?

Antibiotics and antimicrobial supplements can disrupt the microorganisms in your gut microbiome. We recommend waiting four weeks or longer after ceasing your supplement or antibiotic course before taking your sample.

Can I provide a sample with visible blood present?

Yes, you can provide a sample with visible blood, though it's preferred to wait until bleeding resolves. Visible blood may result in a positive faecal occult blood reading. Confirm with your practitioner to ensure proper interpretation.



Should I stick to my regular diet and lifestyle habits before sampling?

If you would like to see what your 'normal' gut microbiome looks like, stick to your normal habits for at least two weeks prior to sampling. The microorganisms inhabiting your gut are quite stable over time (in the absence of any major disruptions) and it is only their abundance that will change based on your diet and other habits.

Can I provide a liquid stool sample?

Yes, you can still send a liquid stool sample for analysis. However, a liquid stool sample may impact result accuracy which will be noted on your report.

Can I provide a sample if I have been taking nonsteroidal anti-inflammatory drugs (NSAIDs)?

It is better to take a sample when you have not been taking NSAIDs in the few days prior. You can still send a sample if you have been taking NSAIDs, but this will impact the level of calprotectin reported. Please advise your healthcare professional so this can be considered in the report interpretation.

For answers on more Frequently Asked Questions visit our website **co-biome.com** or contact the Invivo Customer Service team on **0333 241 2997** for more information.



Symbol Glossary



In vitro diagnostic
medical device



Batch Code



Consult instructions for use



Do not re-use



Keep dry



Authorized representative
in the United Kingdom



Catalogue number



Manufacturer



Storage conditions



Keep away from sunlight



PRODUCT STORAGE

The collection kit must be stored in its original package at a temperature between 5°C and 30 °C until the time of use.

Do not overheat.

Do not freeze your devices prior to use.

If incorrectly stored, its effectiveness will be compromised.

LIMITATIONS

MetaXplore Stool Sample Collection Kit is not intended for users under 18 years of age.

WARNINGS AND PRECAUTIONS:

1. For in vitro diagnostic use.
2. Do not sample faeces from the toilet, faeces mixed with urine, menstrual blood or water.
3. Caution is recommended in using antacids, barium, bismuth, anti-diarrheal medication, antibiotics, histamine, nonsteroidal anti-inflammatory drug or laxatives prior to collection of the specimen.
4. Do not leave the device unattended.
5. Not suitable for rectal sampling.
6. Do not use after the expiry date printed on either device 1 or 3.
7. This product is for single use only. Reuse may cause inaccurate results.
8. Not suitable for any other application than intended use.



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The MetaXplore Stool Sample Collection Kit is intended for the sampling of stool and the specimen's transport to the laboratory for analysis.

METAXPLORE™ GI PLUS IS ONLY AVAILABLE FOR PURCHASE THROUGH A HEALTHCARE PROFESSIONAL.

The faecal occult blood, quantitative polymerase chain reaction (qPCR) and enzyme-linked immunosorbent assays (ELISA) used in MetaXplore™ GI Plus are diagnostic and are approved for clinical use. The faeces pH assay used in MetaXplore™ GI Plus is for research use only and not to be used as a basis for diagnosis. The metagenomic assays used in MetaXplore™ GI Plus are to determine the microbiome populations and associated functional pathways in a faecal sample. The application is for research use only and is not to be used as a basis for diagnosis. Learn more about the journey we are on to validate this gold-standard technology for clinical diagnosis and application at co-biome.com.

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