

STOOL SAMPLE COLLECTION KIT

CE IVD

PATIENT GUIDE



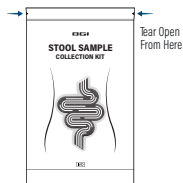
BGI

STEP 1: CHECK AND OPEN THE COLLECTION KIT

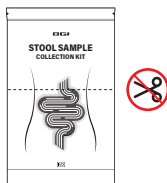
1. Check the date of manufacture of the kit (Figure 1).
2. Check integrity and tightness of the package.
3. Open the package from the top side (Figure 2).



(Figure 1)



(Figure 2)



(Figure 3)



(Figure 4)

- If the kit is expired, or is damaged, **DO NOT** use the kit. Refer to the return instructions and contact information to get a new kit.
- **DO NOT** damage the ziplock strip when open the package.
- **DO NOT** tear open or cut open the package from other places (Figure 3).
- **DO NOT** throw away this collection bag after you open it (Figure 4).

You need this bag to store and return your sample after sample collection.

STEP 2: MAKE SURE YOU HAVE THE FOLLOWING ITEMS

1. Plastic Sample Collection Spoon (Figure 5)
2. Sample Collection Tube With Preservation Fluid Inside (Figure 5)
3. Sample Collection Paper (Figure 5)
4. PVC Disposable Gloves (Figure 5)
5. Funnel (Figure 5)
6. Tube Base (Figure 5)

(Figure 5)

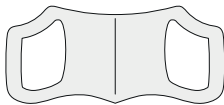
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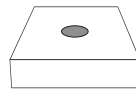
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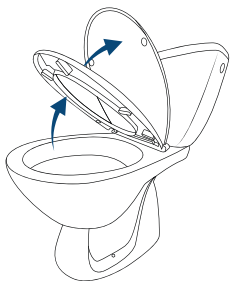
• If any of these items are missing from the kit. Do not use the kit. Refer to the instructions for return and contact information before using the kit.

MOVE ON TO THE NEXT STEPS IF YOU ARE READY TO HAVE A BOWEL MOVEMENT

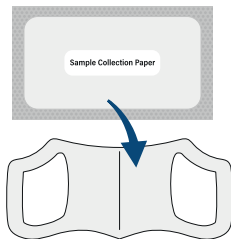
• Collect the sample on a day when you will be able to return the sample **WITHIN 24** hours after collection.

STEP 3: PLACE THE SAMPLE COLLECTION PAPER ON THE TOILET

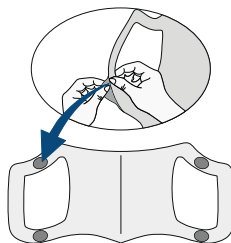
- a. Raise the toilet lid AND seat (Figure 6).
- b. Open the package and take out the sample collection paper (Figure 7).
- c. Peel off the protective films on the sample collection paper to expose the adhesive strips, as shown (Figure 8).
- d. Place and stick the adhesive strip of the sample collection paper over the toilet rim (Figure 9).



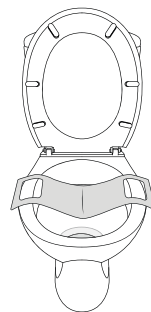
(Figure 6)



(Figure 7)



(Figure 8)

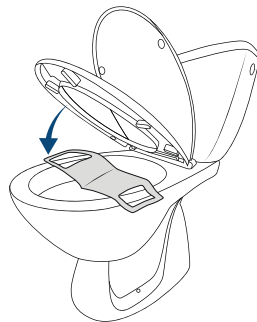


(Figure 9)

STEP 4: HAVE A BOWEL MOVEMENT

If you have problems sitting and standing while using the toilet, get assistance.

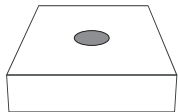
- a. Lower the toilet seat onto the sample collection paper (Figure 10).
- b. Sit on the toilet and have the bowel movement on the sample collection paper, make sure the sample collection paper catches the stool sample.
 - Try to keep urine from getting onto the sample collection paper and stool sample.
 - **DO NOT** throw any toilet paper onto the sample collection paper or stool sample.



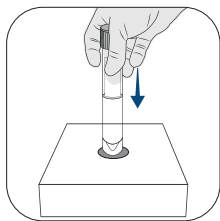
(Figure 10)

STEP 5: PLACE THE COLLECTION TUBE ON THE TUBE BASE

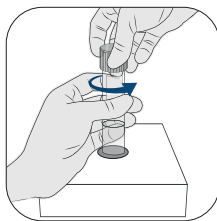
- a. Put on the gloves and take out the tube base (Figure 11).
- b. Place the collection tube on the tube base (Figure 12).
- c. Open the tube by turning the cap counterclockwise. Hold the tube with your other hand if needed (Figure 13).
- d. Take out the funnel and insert it into the tube (Figure 14).



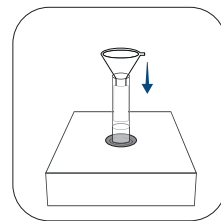
(Figure 11)



(Figure 12)



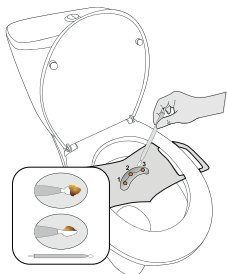
(Figure 13)



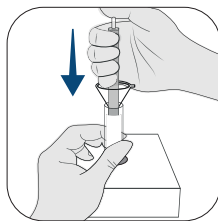
(Figure 14)

STEP 6: COLLECT THE STOOL SAMPLE WITH THE COLLECTION SPOON AND DEPOSIT THE SAMPLE IN THE COLLECTION TUBE

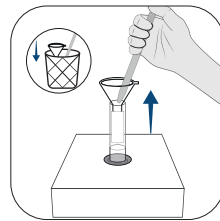
- Use the collection spoon and collect one full spoon of stool sample from two or three different areas on the surface of the stool (Figure 15).
- Insert the spoon with the stool sample back to the collection tube which was placed on the tube base. Push the spoon to ensure the sample is fully submerged in the preservation fluid. Press on the top of the spoon handle to detach the spoon from the spoon handle (Figure 16).
- Gently pull the spoon handle out of the collection tube. The spoon handle and funnel can be discarded (Figure 17).



(Figure 15)



(Figure 16)



(Figure 17)

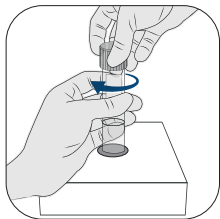
STEP 7: CLOSE THE COLLECTION TUBE AND FLUSH YOUR TOILET

a. Screw the cap shut by turning it clockwise (Figure 18).

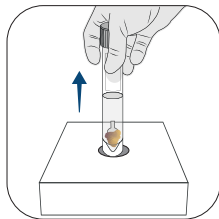
- If the cap is not closed and tightened properly, the liquid could leak out of the tube.

b. Gently pull the closed collection tube out of the tube base. The tube base can be discarded (Figure 19).

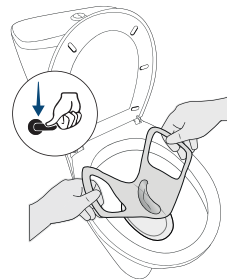
c. Flush the toilet along with the flushable sample collection paper (Figure 20).



(Figure 18)



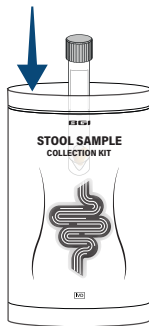
(Figure 19)



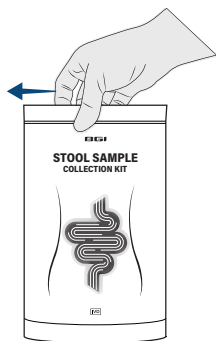
(Figure 20)

STEP 8: RETURN THE COLLECTION TUBE WITH THE STOOL SAMPLE

- Place the collection tube into the collection bag (Figure 21).
- Seal the collection bag. The gloves can be discarded (Figure 22).
- Follow the return instructions and refer to contact information to return the package.
 - Make sure your stool sample is returned within 24 hours after collection.



(Figure 21)



(Figure 22)

GENERIC PRODUCT NAME

Stool Sample Collection Kit

PACKAGE SIZE

One test per collection kit

CATALOGUE NUMBER

MFG010037

INTENDED PURPOSE

This collection kit is intended to be used for the collection, transportation, and storage of human stool samples. It is not automated. The kit is intended to be used by a layperson to collect and mail a stool sample to a clinical laboratory for in vitro diagnostic testing.

PRINCIPLE OF THE PROCEDURES

This product is designed for human stool sample collection, transportation, and storage. The preservation fluid in the tube contains <30% sodium chloride solution (NaCl) and other ingredients. Preservation Solution can inhibit the degradation of DNA and inhibit the growth of bacteria by adjusting pH and high salt ions.

ITEMS IN THE COLLECTION KIT

GENERIC PRODUCT NAME	Quantity	Description
Patient Guide	1	English language collection kit instructions
Plastic Sample Collection Spoon	1	The spoon has a detachable bowl
Sample Collection Tube	4 ml preservation fluid per collection tube, 1 collection tube	The preservation fluid in the tube contains <30% sodium chloride solution (NaCl)
Sample Collection Paper	1	/
PVC Disposable Gloves	1	/
Funnel	1	/
Tube Base	1	/

COLLECTION KIT STORAGE AND SHELF LIFE BEFORE USE

Please store the stool sample collection kit at 2-30 °C. The shelf life of the product is one year. Check to make sure that the kit is not expired. Check to make sure that the collection tube was closed when delivered. After the tube is opened, the preservation fluid will last for 6 months when stored at 2-30 °C. Please keep the kit away from heat and direct sunlight. Make sure you keep the kit away from children.

COLLECTION KIT STORAGE AFTER USE

Please return your stool sample collection kit within 24 hours after collection. The sample should be tested in the laboratory no more than seven days after the collection date, including the time allotted for sample transportation, those conditions apply to samples that are stored and transported at 2-30 °C.

SAMPLE TRANSPORTATION

Please return the sample as soon as possible, no more than 24 hours after sample collection.

SAMPLE STORAGE AFTER ARRIVAL AT THE TESTING LABORATORY

The sample can be kept at room temperature for seven days after being collected, including the time allotted for sample transportation. After seven days, the sample must be stored in the laboratory at low temperature (below -20 °C) for no more than 12 months.

WARNING AND PRECAUTIONS

- This product cannot be re-used.
- This product is only suitable for the collection, transportation, and storage of stool samples.
- The fluid in the collection tube is not for human consumption. If you swallowed it, please seek medical attention immediately.
- If the fluid gets in your eyes or on your skin, flush the area with water.
- Do not pour the fluid out of the collection tube.
- Keep the collection kit away from children.

Contact Details



Manufacturer

BGI Europe A/S.

Manufacturer Address

Ole Maaløes Vej 3, DK-2200 Copenhagen N, Denmark.

Contact Information

Service Hotline: Copenhagen, Denmark: 0045-80300800/ 0045-70260806

Website: www.bgi.com/global

Manufacturing Site

BGI Biotechnology (Wuhan) Co., Ltd.

Site Address

Building B2, B1, Zone B/C/D, Wuhan National Bioindustry Base, No.666
Gaoxin, Avenue, East Lake High-tech Development Zone, Wuhan, Hubei,
430075, China.

Date of release

This manual was released on 08-09-2022

Instructions Document Version	Revision Date	Change Description
V 1.0	20-11-2021	New Add
V 2.0	22-04-2022	Update description according to IVDR requirements
V 2.1	10-08-2022	Delete "Make sure that the self-sealing strip"
V 3.0	08-09-2022	Make some changes to make it more readable

	CE MARK
	In vitro diagnostic medical device
	Manufacturer
	Contains Sufficient for <n> Tests
	Temperature Limit
	Date of manufacture/country of manufacture
	Use-by Date
	Catalogue number
	Batch Code
	Consult Instructions for Use
	Do Not Re-use
	Keep Away From Sunlight
	Keep Dry

STOOL SAMPLE COLLECTION KIT

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Ole Maaløes Vej 3, DK-2200 Copenhagen N, Denmark.

Website: www.bgi.com/global