### invivo

**INSTRUCTIONS** 

## GI EcologiX™

Please read all instructions carefully before beginning

## GI EcologiX Instructions

#### HAZARDS & PRECAUTIONS

#### Fluid in the eNAT swab is harmful

- + Keep out of the reach of children.
- + Avoid contact with the skin & eyes. If contact is made, wash with clean water thoroughly for 15 minutes.
- + If accidentally ingested: contact your local poison control centre immediately.

#### IMPORTANT INFORMATION

#### TIMING YOUR COLLECTION

- + Your sample needs to be returned to our laboratory between Monday Friday.
- + Your sample must be shipped within 24 hours of collection.
- + Your sample must be returned in the box that your test kit was sent in
  - This is a legal requirement & your <u>sample may be rejected</u> if this step is not followed.
- + Please do not collect your sample if you are menstruating at the time of the sample collection. Wait 1 day after menstruation ceases.
- + If you have had a colonoscopy, please <u>wait 4 weeks post-procedure</u> to take the sample.
- + Do not collect test samples if you have, or suspect you have, COVID-19. Please wait 7 days after symptoms subside before collecting your sample.

#### CONSIDERATIONS

- + It is not recommended that you change any prescribed or regular medications or supplements without seeking advice from a suitably qualified healthcare provider.
- + Some medications or supplements are known to have an impact on the test results. If agreed with your healthcare provider, please follow the preperation guidelines on page 4.
- + Long term antibiotics & probiotics can be continued but usage should be disclosed to your practitioner so they are able to interpret the results with that in mind.

#### RECEIVING YOUR RESULTS

- + The turnaround time for test results is <u>15 working days</u> from the day the sample arrives at our lab.
- + Weekends & bank holidays are not included In the turnaround time.
- + When your results are ready, your healthcare provider will receive an email notification letting them know your results are ready to be downloaded from our secure lab portal.
- + Your results can only be downloaded by your healthcare provider.

EcologiX Instructions

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#### **PREPARATION**

#### 14 DAYS BEFORE COLLECTING SAMPLE

1. Complete (where possible) any courses of short term medications such as antibiotics or antifungals.

#### 7 DAYS BEFORE COLLECTING SAMPLE

- 1. Discontinue (where possible) the use of anti-inflammatories.
- 2. Complete courses of botanical antimicrobials or antifungals.
- 3. Discontinue (where possible) use of probiotics.

#### 24 HOURS BEFORE COLLECTING SAMPLE

- 1. Discontinue (where possible) the use of NSAIDS.
- 2. Discontinue (where possible) use of digestive enzymes.
- 3. Discontinue (where possible) over the counter stomach acid aids such as Rennies or Gaviscon.
- 4. Continue all other medication unless advised differently by your healthcare practitioner.

#### DAY OF SAMPLE COLLECTION

- 1. Ensure you have read & understand all instructions before beginning. If you need any assistance please call our Customer Services team on 0333 241 2997.
- 2. Discontinue (where possible) the use of prebiotics.
- 3. If using steroid cream for the anus, shower & ensure it is completely washed off before completing the test.

#### **CHECKLIST**

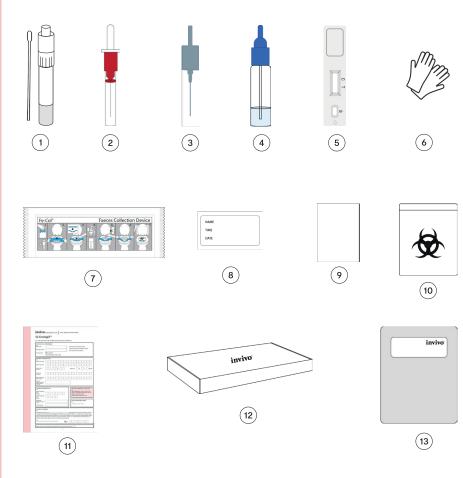
To ensure your samples are not rejected please ensure you have checked off every point in the below checklist.

#### **CHECKLIST**

- Read all instructions carefully before beginning
- Complete test requisition form (TRF)
- Complete Easy-Card H. pylori Antigen Test & record result on TRF
- Place the completed TRF into the side pocket of the biohazard bag
- Complete 3 swabs (following instructions on pages 8-14)
- Ensure the top of the eNAT device has been fully depressed & the liquid has mixed with the sample
- Ensure the 4 small notches at the tip of the ScheBo swab are completely filled and not overfilled
- Place all 3 swabs into the biohazard bag with the absorbent pad & seal the bag
- Place biohazard bag into test kit box
- Put the test kit box into the mailing bag
- Arrange sample return

EcologiX Instructions

#### KIT CONTENTS



- 1. eNAT Collection Swab
- 2. ScheBo® Collection Swab
- 3. Auto MC Collection Swab
- 4. H. pylori Collection Tube
- 5. H. pylori Antigen Device
- 6. Pair of latex-free gloves
- 7. Fe-Col Faecal Collection Device

- 8. Sample Sticker
- 9. Absorbent White Sheet
- 10. Biohazard Bag
- 11. Test Requisition Form (TRF)
- 12. Test kit box (the box your test came in)
- 13. Unpaid Addressed Mailing Bag

#### HOW TO COLLECT YOUR SAMPLE

1. Write in block capitals, using a permanent marker, the following information on the test requisition form the sample sticker.

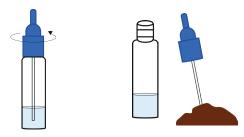
#### Your full name

#### Your date of birth

#### Date & time of collection

- 2. Peel the completed sample sticker <sup>(8)</sup> off its backing & attach to the outside of the biohazard bag.
- 3. Attempt to empty bladder prior to collecting the stool sample.
- 4. Put on the disposable gloves & remove the faeces collection device from its packaging. Gently place the device around the toilet seat. Do not let the collection device touch the water.
- 5. Complete the stool sample onto the collection device . Take care not to contaminate the sample with urine.
- 6. Complete Easy-Card *H. pylori* Antigen test<sup>(4),(5)</sup>. Instructions for this are on page 8 & 9. Record the result on your Test Requisition Form<sup>(1)</sup>.
- 7. Collect the eNAT swab . Instructions for this are on page 10-11
- 8. Collect the ScheBo® swab<sup>2</sup>. Instructions for this are on page 12-13
- 9. Collect the Auto MC swab<sup>3</sup>. Instructions for this are on page 14
- 10. Rip both sides of the faecal collection device <sup>7</sup> above the toilet seat & let the collection device fall into the toilet bowl. Wait 3 minutes until the device is saturated before flushing then dispose of gloves <sup>6</sup> appropriately.
- 11. Place the sample swabs (1,2,3). into the zip-lock side of the biohazard bag (0), with the white absorbent sheet. Seal the bag tightly.
- 12. Place the completed test requisition form into the side pocket of the biohazard bag. Do not place it in the same pocket as the sample.
- 13. The biohazard bag should now include: three completed sample swabs, the white absorbent sheet, & the completed test requisition form the biohazard bag into the test kit box it arrived in.
- 14. Place the test kit box<sup>(2)</sup> into the unpaid, addressed mailing bag<sup>(3)</sup>
- 15. Ship your completed & packaged test kit to us (shipping info on page 15).

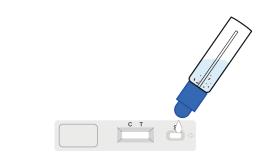
- Unscrew the blue top of the stool collection tube (4).
- Insert the tip of the stool collection tube into the stool sample at a depth of 1cm. Repeat this collection procedure 3 times in 3 separate locations of the stool. Take care not to spill any of the liquid in the collection tube.

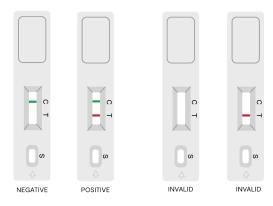


Insert the stool collection tip back into the transport tube & screw closed. Take care to avoid any external contamination of the device. Shake the tube in order to ensure good sample dispersion.



- Remove the Easy-Card  $\emph{H. pylori}$  Antigen device  $^{\textcircled{5}}$  from its sealed bag just before using.
- Tear/snap off the top of the transport tube.
- Dispense exactly 4 drops into the circular window marked with an arrow, avoiding the addition of solid particles with the liquid.





Write your result (Negative/Positive/Invalid) on your Test Requisition Form (11) & dispose of the test. Please contact us if your result is invalid.

GI EcologiX <sup>TM</sup> ALL FIELDS MUST BE COMPLETED IN BLOCK CAPITALS	
FOR INVIVO'S REFERENCE  Sales order:  Ordering cincion:  First requirenct  O Gif Coolego <sup>(4)</sup> O Hubbh Markers Only (EUSA)	O Calgrowcoth Standalone (EUSA) O Percretic Dataset Standalone (EUSA) O Gl Microbiome Only (pPOS)
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PATIENT CONSENT  (bysterot/responsible party). The prospect of proventiation or soon sense and provided that the prospect of the provided that the provided	disclosure of the results to the ordering clinician nar myself. I can confirm that invivo Clinical Ltd. has not ider.

If your result is positive, you may choose to let your healthcare provider know in the interim. The result will be reported with all of the other microbiome & host marker analysis at the end of the specified turn around time.

EcologiX Instructions

#### **eNAT SWAB INSTRUCTIONS**



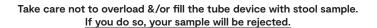
- 1. Peel open the protective packaging of the  $eNAT^{(1)}$  swab.
- 2. Remove the lid of the tube & place the tube upright in close proximity.

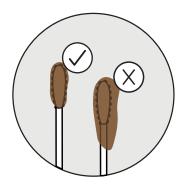


Insert the swab into the stool sample & twist.

Saturate the entire tip of the swab with the stool sample.

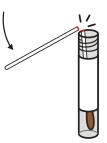
Repeat this collection procedure 3 times in 3 separate locations of the stool.





Your sample will be rejected if the swab is overloaded or the tube device is overfilled with stool sample

#### **eNAT SWAB INSTRUCTIONS**



 Place the swab (fabric tip first) into the transport tube & snap the swab handle against the side of the transport tube.

Take care to avoid any external contamination of the device.

There is an indented line along the swab handle to mark the point at which the swab will snap.

Discard the swab handle.



 Hold the tube in a vertical position, align the cap, & firmly push & screw the cap, stop when you hear a "CLICK". Ensure the cap is screwed on tightly.



- 6. Press the plunger until it is <u>completely</u> inside the cap.
- 7. Shake the transport tube to ensure the liquid coats the fabric tip of the swab.

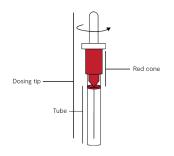
#### LIQUID MUST VISIBLY MIX WITH SAMPLE

Sample will be rejected if the plunger is not fully depressed, the cap is not screwed on correctly or the vial is leaking.

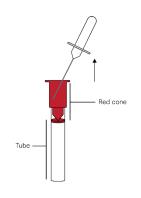


GI EcologiX Instructions

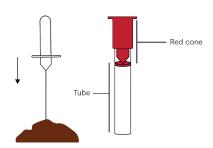
#### ScheBo® SWAB INSTRUCTIONS



Turn the white dosing tip of the ScheBo® Swab<sup>2</sup> anti-clockwise.



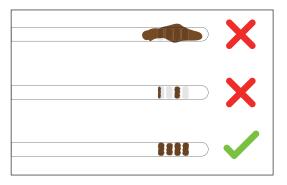
Remove the dosing tip from the transport tube by pulling it upwards.



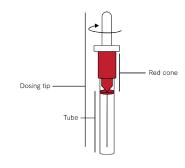
- Insert the dosing tip into the stool sample to a depth of 1 cm ensuring all notches on the tip contact the stool & then remove.
- Repeat this collection procedure 3 times in 3 separate locations of the stool.

#### ScheBo® SWAB INSTRUCTIONS

Your sample should completely fill in the 4 small notches at the tip of the swab as pictured below.



Your sample will be rejected if this device is insufficiently filled or overfilled



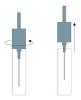
- 5. Insert the dosing tip into the transport tube via the red cone. Take care to avoid any external contamination of the device.
- Turn the dosing tip clockwise until the tip locks into the red cone.

# GI EcologiX Instructions

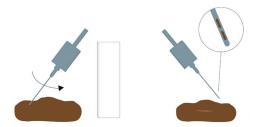
15

#### Auto MC SWAB INSTRUCTIONS

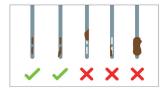
 Unscrew the top of the Auto MC Swab<sup>3</sup> tube anti-clockwise to expose the sampling tip.



- 2. Insert the sampling tip of the swab into the stool sample & scrape the tip along the stool sample.
- Ensure both notches on the swab are filled. The sampling tip should be covered in stool, but the stick of the swab should not be coated with stool.



 If there is an excessive amount of stool on the swab (any more than the notches filled on the sampling tip) remove excess with toilet paper prior to returning the swab to the tube.



- 5. Replace the swab into the sample tube & twist clockwise to close securely.
- 6. Once the completed swab is in the tube, do not remove & re-collect.

Please note the turnaround time for test results Is 15 working days from the date the sample arrives at our lab.

Weekends & bank holidays are not included In the turnaround time.

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