

Direct Sampling with the CALEX® Extraction Device



Your Test

Your healthcare professional has asked you to complete one or both of the following tests:

- **Faecal Calprotectin** – helps identify any inflammation in your gut.
- **Faecal Elastase** – helps assess how well your pancreas is working.

Intended Use

A single-use, home sampling kit for collection and transportation of a faecal (poo, or stool) sample to the laboratory for analysis.

What Sample is Required?

For Calprotectin:

It is advisable to use the first bowel movement of the day because this is likely to contain the highest level of calprotectin, if it is present.

For Elastase:

A formed poo sample (solid or semi-solid) is preferable for this test.

Avoid using a liquid or watery poo sample, as it may dilute the enzyme and lead to inaccurate results. If possible, wait until a more formed poo sample can be collected.

Contents:

1x CALEX device

1x Instruction for use (this document) with detachable label

1x clear plastic bag

Key Things to Remember

- Do NOT use the CALEX beyond the stated expiry date.
- The poo sample must not come in contact with the toilet water due to bleaches and disinfectants.
- Do not get urine in the sample as this will dilute it.
- Read the instructions carefully before you start.
- For Elastase: A formed sample is ideal.

How to Collect Your Sample

BEFORE YOU BEGIN...

Write the date of sample collection on the label. Also write your name, date of birth and NHS number if this is not already on the tube.

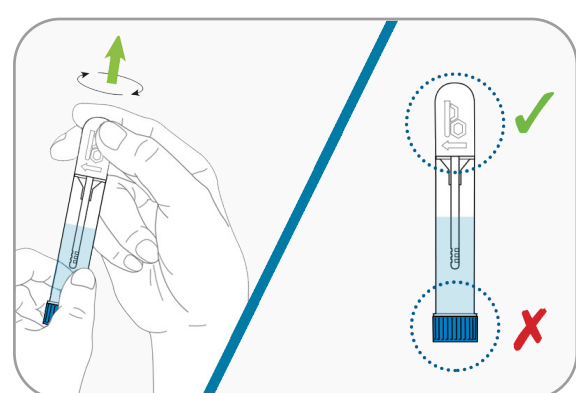
1 COLLECT THE POO SAMPLE



There are a number of ways to collect your poo sample:

- A clean takeaway container, paper or foil plate.
- **Loosely** draped cling film placed over the toilet towards the back to form a dip. (Do not flush after use).
- A plastic bag or glove covering your hand.
- **Elastase only** – Use a formed sample where possible.

2 PREPARE THE CALEX CAP



Holding the CALEX Cap tube with the white cap pointing upward remove the sampling pin by simultaneously turning clockwise and pulling up the white cap.

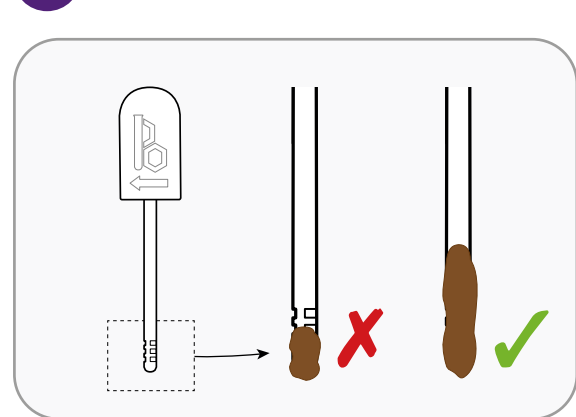
3 TAKE THE SAMPLE



Dip the sampling pin into the poo and twist. Repeat this process three to five times in different places in the sample. Scan the QR code to watch a video on how to deal with different sample consistencies.

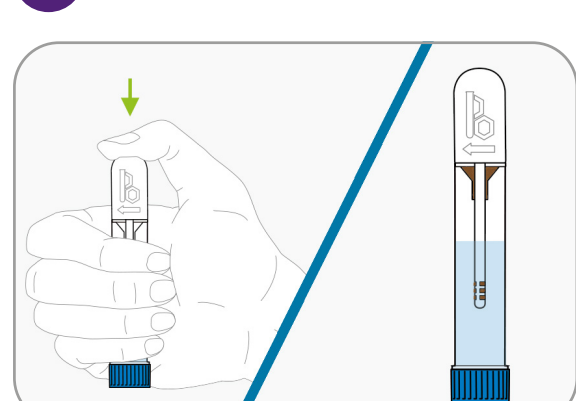


4 CHECK THE SAMPLE



Make sure all the grooves are completely filled on the end of the sampling pin.

5 RE-SEAL THE CALEX CAP



Replace the sampling pin back into the CALEX Cap tube and push firmly into the locking position (you will feel and hear two clicks).

6 DO THIS ONLY ONCE

Once complete do not remove the sample pin or repeat the collection process as this will lead to inaccurate or incorrect results. Please return your sample in the plastic bag provided as quickly as possible to your GP or hospital laboratory.



DO NOT UNSCREW THE BLUE CAP and DO NOT EMPTY THE LIQUID FROM THE CALEX CAP

Liquid contains preservative which may cause allergic skin reactions. If skin irritation or rash occurs: Get medical advice/attention.

Checklist

- Ensure the white cap is replaced securely (you will hear two clicks).
- Ensure the CALEX® tube is clearly labelled with your name, date of birth, NHS number, date of sample collection and indicate if the sample was liquid (Yes/No).
- Put the CALEX® tube and the GP request form into the plastic bag and return as directed to the GP or hospital laboratory, as quickly as possible.

Access to Alternative IFU Formats

Scan the QR code to visit our website where you can find different versions of the IFU, including:

- Narrated step-by-step.



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**Please Do NOT
send the
completed
sample to this
address**