Read thoroughly before getting started
Stool collection
Step-by-step instructions

Packing and shipping
Step-by-step instructions

Please read booklet carefully

Persistent diarrhea can be frustrating

It can also be frustrating to not know why you have persistent diarrhea, when episodes of diarrhea last for more than 2 weeks. Persistent diarrhea may be a symptom of many gastrointestinal (GI) conditions, which can make it challenging to diagnose. With the PROMETHEUS® IBcause™ Diagnostic Test, your doctor can help you get answers. This 2-part blood and stool test detects many common causes of persistent diarrhea. This guide provides instructions to successfully complete the stool sample part of PROMETHEUS IBcause.

*The PROMETHEUS® IBcause Diagnostic Test is recommended for patients with ongoing diarrhea (which may be referred to as persistent or chronic).

With PROMETHEUS IBcause, your doctor can help you get answers.

Follow the “Stool collection” and “Packing and shipping” instructions in the pocket above.

Watch the overview video at IBcause.com

Device description: This product is intended to aid in the collection and transportation of stool samples, for use in performing in vitro diagnostic testing. Any other use is prohibited.
What’s included

Contents of the PROMETHEUS® IBcause™ kit for collecting your stool sample

1 NanoCool® Cooling Pack

2 Paper Toilet Liners with adhesive strips

2 pairs of disposable Gloves

1 Stool Sample Container with Plastic Scoop and 1 Resealable Plastic Bag

1 Prepaid Shipping Label already adhered to the box

1 Patient Information Card

1 Instruction Guide

Read thoroughly before getting started

1 Small Gel Pack Should NOT be removed from the box.

Patient information card

After you have collected your stool sample, you must complete this card with your sample collection information and include it with your shipment. Use a ballpoint pen and write on a hard, flat surface.

Have any questions? Call us at 888-423-5227, Option 1.

EXAMPLE

Jane Doe

First name

Last name

03/10/85

Date of birth (mm/dd/yy)

01/15/17

Sample collection date

abc1234

Patient Requisition ID

Please PRINT your information as shown in the example to the left.

Prometheus diagnostic services provide important information to aid in the diagnosis and management of certain diseases and conditions. How this information is used to guide patient care is the responsibility of the physician.

Assays and methods within this test may be covered by one or more US pending or issued patents. For details, please go to www.prometheuslabs.com.
Get ready

Before collecting your stool sample

Read this entire guide
• Have any questions? Call us at 888-423-5227, Option 1

Choose your collection day
• Pick a weekday where you can both:
  - Collect and package your stool sample without rushing
  - Ship your stool sample the same day you collect it

![Calendar]

Find a local FedEx®
• You must drop off your stool sample (or schedule a FedEx pickup) the same day you collect it
  • A prepaid shipping label has already been adhered to the box

⚠️ Your stool sample can only be shipped via FedEx.

⚠️ Stool samples cannot be shipped on weekends or holidays—so plan accordingly.

Prepare to collect your sample
• Remove the PROMETHEUS® IBcause™ kit items
• Place needed items near the toilet for easy access

![Checklist]

![FedEx Logo]
Important do’s and don’ts

**Do’s**
- Do attach the Paper Toilet Liner in advance for ease of use
- Do ensure the Paper Toilet Liner is secured to the toilet bowl
- Do wear the provided disposable Gloves when collecting your stool sample
- Do ship the same day that your stool sample is collected
- Do place the Patient Information Card in the box before shipping
- Do review the Checklist label

**Don’ts**
- Don’t collect a firm stool sample (only loose stool should be collected)
- Don’t let the Paper Toilet Liner touch the toilet water
- Don’t collect your stool sample from the toilet water; collect from the Paper Toilet Liner only
- Don’t contaminate the outside surface of the Stool Sample Container (if soiled, wipe clean with a paper towel)
- Don’t activate the NanoCool® Cooling Pack until you have collected your stool sample
- Don’t bring the kit back to your doctor’s office or laboratory; you must ship it via FedEx® for testing
- Don’t remove the Small Gel Pack from the box
FAQs

If you have any concerns regarding the PROMETHEUS® IBcause™ Diagnostic Test, call us at 888-423-5227, Option 1.

What if I was unable to collect a stool sample as instructed, or tore the Paper Toilet Liner?
Don’t worry. Simply use the second Paper Toilet Liner the next time you use the bathroom. If you still have concerns, call us at 888-423-5227, Option 1.

What if I collect my stool sample at night and cannot ship it until the next day?
You should only collect a stool sample if you are able to ship it on the same day it was collected. If you have any concerns about shipping your sample, call us at 888-423-5227, Option 1.

Can I place the NanoCool® Cooling Pack in the freezer?
No, and you should only activate the Cooling Pack after your stool sample has been collected.

Do I need to collect a loose bowel movement for my sample?
Yes. It is preferable for you to collect and ship a loose stool sample. Since loose stools are common with any type of diarrhea, this should not be difficult for you. However, please do not collect a very watery (all liquid) stool sample.

What if I lose or damage the shipping box?
Call us at 888-423-5227, Option 1. We will be happy to assist you.

How will I receive my test results?
Your doctor will share your PROMETHEUS IBcause test results with you once they are ready. Visit IBcause.com to sign up for the patient portal to access your results electronically.

When will my doctor get my results?
Your doctor will typically receive your PROMETHEUS IBcause test results in about a week.

CAUTION: Federal law restricts this device to sale by, or on the order of, a physician.

1.0 DEVICE DESCRIPTION
1.1 This product is intended to aid in the collection and transportation of stool samples, for use in performing in vitro diagnostic testing. Any other use is prohibited.
1.2 Kit contents include:
   1.2.1 1 Instruction Guide
   1.2.2 1 Patient Information Card
   1.2.3 1 Prepaid Shipping Label already adhered to the box
   1.2.4 2 pairs of disposable Gloves
   1.2.5 2 Paper Toilet Liners with adhesive strips
   1.2.6 1 Stool Sample Container with Plastic Scoop
   1.2.7 1 Resealable Plastic Bag for sample container
   1.2.8 1 NanoCool® Cooling Pack
   1.2.9 1 Small Gel Pack. Should NOT be removed from the box.

2.0 WARNINGS & PRECAUTIONS
2.1 Collected stool samples should be immediately packaged and shipped per instructions provided in this guide. Please delay collection of sample until the day that shipping can be performed.
2.2 Do not activate the NanoCool® Cooling Pack until the sample has been collected, packaged, placed in the shipper, and is ready for return shipping.
2.3 This kit contains no known carcinogenic, mutagenic, or toxic materials that could result in sensitization or allergic reaction.
2.4 Please see Do’s and Don’ts section for additional detailed precautions.

3.0 PRODUCT SUPPORT
3.1 Please consult your physician or healthcare provider to discuss your specific medical condition or any challenges you may have or encounter in completing the requested sample collection.
3.2 For additional information or questions concerning this kit or its use, or to provide feedback on kit performance, please contact Prometheus Laboratories Inc. at 888-423-5227, Option 1.
We’re here to help

Have additional questions?

• Go to IBcause.com
• Call us at 888-423-5227, Option 1


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Stool collection
Step-by-step instructions

1. Lift the toilet seat and wipe the toilet bowl rim (with dry toilet paper or a paper towel) until dry.
   • The Paper Toilet Liner will not stick to a wet surface

2. First, remove protective tape covering from the CENTER BACK FLAP.

3. Then, adhere the flap to the back of the toilet bowl (sticky side down).

4. Remove protective tape coverings from the 2 REAR FLAPS. Now adhere the flaps to the top of the toilet bowl rim, allowing the center area of the liner to hang just inside the toilet in a “cup” shape.
   • The Paper Toilet Liner should never touch the toilet water. If this occurs, use the second liner provided
   • When adhered correctly, the liner will have a “cup” shape. There should also be enough room in front of the secured liner to discard soiled toilet paper into the bowl after your bowel movement

5. FRONT FLAP
   Remove protective tape coverings from the 2 FRONT FLAPS and adhere to the top of the toilet bowl rim.

6. CENTER AREA
   Once the Paper Toilet Liner is secured, lower the toilet seat.

Before your bowel movement
attach the Paper Toilet Liner to your toilet bowl

TURN OVER for further instructions

IMPORTANT: You must ship your stool sample the same day it is collected.

Have any questions? Call us at 888-423-5227, Option 1.
Collect your stool sample

Follow these steps for best results

Thoroughly wash your hands with soap and water.

1. Thoroughly wash your hands with soap and water.

2. Put on provided disposable Gloves.

3. Have a bowel movement.
   - When collecting your stool, it is best to avoid contact with toilet water and/or urine.
   - Leave the Paper Toilet Liner in place (you will collect your stool sample while it is attached).
   - Do not place soiled toilet paper on the liner (discard through the opening in front of the liner or use the trash) and do not flush the toilet until after you have collected your sample.

4. Unscrew the Stool Sample Container lid. Do not unscrew small white screw cap (for laboratory use only).
   - Use the attached scoop to collect the stool sample.

5. Place your stool sample into the Stool Sample Container.
   - Fill with a minimum of 30 mL of stool (clearly marked on container side); typically 1-2 scoops.
   - Screw the lid on tightly.
   - Do not contaminate the outside surface of the Stool Sample Container (if soiled, wipe clean with a paper towel).
   - Do not reopen the Stool Sample Container once it is closed.

6. A minimum of 30 mL

Step 7. Insert the Stool Sample Container back into the Resealable Plastic Bag. Make sure the bag is sealed completely.

First, flush once to dispose of soiled toilet paper. Then, remove the Paper Toilet Liner and flush a second time.
   - Flushing the toilet twice is suggested to ensure disposal.
   - Remove and discard Gloves in the trash.

Step 8. Fill out the provided Patient Information Card.

Step 9. Now, please see the detailed “Packing and shipping” instructions sheet.
Pack, seal, and ship your sample for testing with the provided prepaid overnight FedEx® label.

Have any questions? Call us at 888-423-5227, Option 1

Remember: Your stool sample can only be shipped via FedEx.

Stool samples cannot be shipped on weekends or holidays—so plan accordingly.

Turn over to start
Just a few final steps

1. Write your sample collection date and time on the Stool Requisition Form, if you were given one.

2. Remove the NanoCool® Cooling Pack from the box. Flip it over and place foil side down on a hard, flat, and clean surface.
   - Do not place White Activator Button side down

3. Remove Foam Activator Button Protector and dispose of it.
   - White Activator Button should be visible

   - Use moderate force (do not use an object to press down)

5. After about 20 seconds, the NanoCool® Cooling Pack will start to cool.
   - To confirm cooling has begun, touch the NanoCool® Cooling Pack surface near the Activator Button
   - NanoCool® logo should turn blue

6. Pack the Stool Sample Container on top of the Small Gel Pack adhered to the bottom of the box.

   Now place the NanoCool® Cooling Pack into the box with the Activator Button face down and foil side up.

   Then place the Patient Information Card on top of the NanoCool® Cooling Pack.
   - If you were given a Stool Requisition Form, also place it on top of the NanoCool® Cooling Pack

   Please refer to the checklist located on the inside lid of the box.
   - If everything has been completed, you are ready to seal the box

7. Peel the tape strip on the edge of the box, tuck in the side flaps, and then press down on the front of the box to secure.
   - Press firmly to ensure box is sealed

Take your box to a FedEx® shipping station or schedule a pickup and you’re done!

Remember: Your stool sample can only be shipped with FedEx. Stool samples cannot be shipped on weekends or holidays—so plan accordingly.