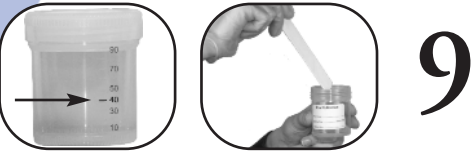


Step 2:

Collection instructions for the white-top cup

Continued from Steps 1 - 8 on preceding panel



9

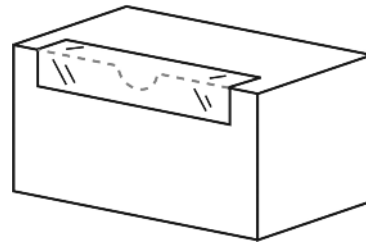
Look closely at the empty white-top cup. Find and mark the 40-ml line (about 1/3 up from the bottom). Open the empty white-top cup. Using the flat wooden stick provided, pick up several portions of stool from contrasting areas in the collection tub. Add sufficient stool sample to reach the 40-ml line. Using the wooden stick, mix stool in white-top container. Recap the container and check to ensure it is securely fastened. **Do not overfill.** Repeat steps 5 and 6 from Day One instructions.

Step 3:

Ship the stool specimen to the lab

Specimen must be returned in the Genova Diagnostics kit box for correct delivery to the lab. Not following these instructions may result in a shipping charge.

- Plan to ship the specimen **Monday – Friday overnight delivery only.**
- Call 1.800.GoFedEx (1.800.463.3339) to schedule shipping. When the automated system asks “How may I help you?” say “Return a Package.” Tell the FedEx representative “I am using a billable stamp” and they will walk you through the process and make it easy.
- **Place the following items in the FedEx clinical lab pack:** Day One Biohazard bag, containing 1 filled specimen tube; Day Two Biohazard bag, containing 1 filled specimen tube; Day Three Biohazard bag, containing 3 filled specimen tubes and 1 filled white-top cup; Requisition form, completed and signed.
- **Place the FedEx clinical lab pack in the test kit box.** Using the enclosed tape strip, seal the front of the box lid to the notched, front edge of the box as pictured below.



- **Print your name and address** in the section marked “From” on the FedEx billable stamp. DO NOT mark or write in any other sections.
- **Place the FedEx billable stamp on the top of the box lid**, retaining your copy of the tracking number for your records.
- Keep your shipment and tracking numbers for future reference and tracking purposes.

CDSA^{2.0}™ (Purge Random)

Patient Instructions

IS-2738



Check Your Kit

- | | |
|---|--|
| A - 3 Collection tubs plus 1 lid with printed instructions for use | C - 1 Requisition Form (to be completed and signed) |
| B - 1 Holder to suspend collection tubs over toilet (provided separately from kit) | D - 1 Prepaid mailing envelope |
| E - 1 Piece of shipping tape | |
| Day One Bag
<i>Purge Collection</i> | Day Two Bag
<i>Random Stool Collection</i> |
| F - 1 Green-top SAF tube | J - 1 Green-top SAF tube |
| G - 1 Glove | K - 1 Glove |
| H - 1 Disposable dropper | L - 1 Absorbent pad |
| I - 1 Absorbent pad | |
| Day Three Bag
<i>Random Stool Collection</i> | |
| M - 1 Green-top SAF tube | |
| N - 1 Yellow-top Cary Blair tube | |
| O - 1 Orange-top Formalin tube | |
| P - 1 Empty white-top cup | |
| Q - 1 Flat wooden stick | |
| R - 1 Glove | |
| S - 1 Absorbent Pad | |

- If any items are missing or expired, call Client Services at 800.522.4762 and press “1”.
- Keep the kit box for shipping your specimen to the lab.

Step 1:

Important things to know and consider

- If any liquid is spilled from the vials, stop the test immediately. Any liquid lost from a vial **invalidates** the test results. **Call Client Services at 800.522.4762 and press "1"** to obtain new vial(s).
- **Extreme care** should be used when opening and filling vials. Do not spill or discard any tube fluid. Avoid contact of the eyes or skin with the fluid in the tube. For contact with eyes, wash thoroughly for 15 minutes. For skin contact, wash thoroughly with soap and water. Do not inhale or ingest liquid. For accidental ingestion, contact your healthcare provider at once.
- Talk to your healthcare provider before stopping any prescribed substance.
- This kit does *not* contain a laxative. A common over-the-counter laxative such as magnesium citrate may be used. Follow directions on the manufacturer's label for age and dosage instructions as well as pertinent warnings. Consult with your healthcare provider for any questions you may have related to the appropriate choice and/or use of a laxative for this test. On the day of your first collection, **do not eat or drink anything except water before taking the laxative**. You may resume your normal eating and drinking habits 1 hour after taking the laxative.
- The following are **interfering substances** and should be discontinued **unless directed otherwise by your physician**: bentonite clay, betaine HCL, castor oil, mineral oil, rectal suppositories. If you are taking a medication that isn't listed as an interfering substance, ask your health care professional before stopping any prescribed substance.
- We do not suggest collecting during an acute gastrointestinal infectious illness. Wait at least **4 weeks** from colonoscopy or barium enema before beginning the test.
- **2 weeks before test:** If taking antibiotics or antifungals – or taking beneficial flora supplements (acidophilus, etc.) or consuming food products containing beneficial flora (e.g. Activia®) – it is recommended that you **wait at least 14 days** after your last dose before beginning the test (unless instructed otherwise by your physician). There may be times when you healthcare provider prefers that you stay on one of these agents (e.g. acidophilus) in order to evaluate its effectiveness. Follow your healthcare provider's recommendation.
- **Eat your usual diet** during the 2-3 days prior to stool collection, ideally including a small amount of fatty foods (e.g. butter or salad oils) and protein-rich foods, so that we may assess how your body processes them. Contact your healthcare provider with any questions.
- **2 days before the test:** It is recommended that you discontinue use of over-the-counter suppressants of inflammation like aspirin and/or non-steroidal anti-inflammatory drugs (ibuprofen, Advil®, Motrin®, Nuprin®) unless requested to continue by your physician.

Schedule & Prepare for Stool Collection

- **Plan for Monday-Friday collection only: Specimens must be received in the laboratory within 4 days of Day 3 collection.** If you take the test over the weekend, call FedEx to schedule a pick-up on Monday.
- **Contact FedEx and schedule to ship the specimen overnight delivery** Monday - Friday.
- **Storing your samples:** Send in your samples as soon as you complete the test. Store samples at room temperature or refrigerate. **Do NOT freeze.**
- **Complete the Requisition Form** with all patient and billing information. Be sure it is signed by the Patient/Responsible Party and the healthcare provider.

Prepare your specimen using these collection tubes on these days:

Day One:	1 Green-top SAF tube
Day Two:	1 Green-top SAF tube
Day Three:	1 Green-top SAF tube 1 Yellow-top Cary Blair tube 1 Orange-top Formalin tube 1 Empty white-top cup

Step 2:

Stool Collection

Not following these instructions may affect the test results.

Day One (Purge Collection)



1

Write your name and the date the specimen was collected on the green-top SAF tube label from the Day One biohazard bag. After doing this, take the laxative your physician has provided or recommended at the specified dosage. Drink 8 oz. of water afterwards.



2

Within 2-4 hours (on average) you should experience mild diarrhea. Pass any formed or soft stool until you have a watery bowel movement. Collect a watery movement using one of the collection tubs provided in the kit.



3

Open the green-top tube. Stir the sample lightly with the disposable dropper. Use the dropper to collect from contrasting areas of the sample, including blood, pus, etc. Transfer liquid stool into the tube. Add sufficient stool sample for the stool and tube liquid to reach the red "fill" line, as shown on the label. **Do not overfill.**



4

Recap the tube securely. Then, shake well until mixed thoroughly.



5

Be certain cap is tight for shipping. Place your filled tube in the Biohazard bag corresponding to the day's collection. Seal the bag securely. **Do not freeze the sample.** Discard glove and used tub.

Day Two (Random Stool Collection)



6

Write your name and the date the specimen was collected on the green-top SAF tube label from the Day Two biohazard bag. If unable to collect on consecutive days, resume the test on the next day you have a bowel movement.



7

Pass urine into the toilet if necessary. Pass stool into one of the collection tubs provided in the kit. Do not let urine or water from toilet touch the stool specimen. Repeat steps 4 through 6 from the Day One instructions.

Day Three (Random Stool Collection)



8

1-5. Repeat the same collection process as Day Two. Using one stool specimen, fill all three tubes first, and then fill the white-top cup.

Consult your healthcare provider if you have any questions at any time during this test.

Please see next panel for additional instructions.