

Home Collection Kit — Instructions for Use

Read all instructions completely before opening any component

DO NOT BEGIN UNTIL YOU HAVE READ EVERY STEP

Collecting out of order, using an expired kit, or mailing an unlabeled tube are the three reasons a sample is most often rejected and has to be recollected.

INTENDED USE Self-collection of a specimen for laboratory testing by a lay user	FOR USE BY Adults 18 and older, or a caregiver	TIME REQUIRED About 15 minutes	READ REVISION DEMO-1
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1 — KIT CONTENTS

Check every item against this list before you start. Do not substitute any component, and do not use a component from a different kit.

QTY	COMPONENT	IDENTIFYING MARK	IF IT IS MISSING OR DAMAGED
1	Collection device, sealed	Blue cap, printed CPD-HC	Stop. Call kit support.
1	Transport tube with preservative	Amber tube, white screw cap	Stop. Call kit support.
1	Specimen identification label	Barcode beginning CPD-	Stop. Do not write your own.
1	Biohazard specimen bag with absorbent sheet	Clear bag, printed symbol	Stop. Call kit support.
2	Alcohol wipes	Individually sealed	Stop. Call kit support.
1	Requisition form	Pre-printed with your order	Stop. Call kit support.
1	Prepaid return mailer	Pre-addressed, prepaid	Stop. Call kit support.
1	This Instructions for Use	Revision DEMO-1	Request a replacement.

2 — WARNINGS AND PRECAUTIONS

- Do not use:** Do not use this kit if the expiration date printed on the box has passed, if any seal is broken, if the transport tube is cracked or leaking, or if liquid has escaped from the tube.
- The transport tube contains a chemical preservative. **Do not drink it, do not pour it out, and do not open the tube before the collection step.**
 - If the preservative contacts skin or eyes, rinse with water and call kit support.
 - Keep all components away from children and pets.
 - Do not collect if you were told to avoid collection at this time for any reason.
 - Do not freeze the kit and do not leave it in a hot vehicle.

3 — BEFORE YOU COLLECT

- Check the expiration date on the kit box.
 - Confirm the name printed on the requisition form is yours.
 - Choose a clean, flat, well-lit surface. Do not use a carpeted surface.
 - Follow any preparation instruction that was provided with your order, such as a fasting or timing requirement.
 - Wash your hands with soap and warm water for at least 20 seconds and dry them completely.
 - Lay out all components in the order shown in Section 1.
- Do not open the transport tube yet.

4 — COLLECTION PROCEDURE

STEP	ACTION	HOW YOU KNOW IT IS CORRECT	COMMON ERROR
4.1	Open the sealed collection device by peeling the pouch from the marked corner. Hold the device by the blue cap only.	The tip of the device has not touched any surface.	Setting the device down on the counter after opening it.
4.2	Collect the specimen using only the supplied collection device, following the technique and duration described in the insert that came with your specific order.	The absorbent portion is visibly saturated.	Stopping early because it seems like enough.
4.3	Unscrew the white cap from the amber transport tube. Set the cap down with the inside facing up. Do not touch the inside of the cap.	Liquid preservative is visible in the tube.	Placing the cap face-down on the table.
4.4	Insert the collection device into the transport tube until it stops. Snap the handle at the marked break line and discard the handle.	An audible snap, and the device sits fully inside the tube.	Forcing the break line at the wrong point.
4.5	Screw the white cap on firmly until it will not turn further.	The cap is flush with the tube shoulder.	Leaving the cap loose, which causes a leak in transit.
4.6	Invert the closed tube gently five times. Do not shake.	The contents are visibly mixed.	Shaking vigorously, which can damage the specimen.

5 — LABELING: THE STEP MOST OFTEN DONE WRONG

1. Write the **collection date** and **collection time** on the specimen identification label using a ballpoint pen. Do not use pencil or marker.
2. Apply the label to the transport tube lengthwise, so the barcode runs along the tube and is not wrapped around it.
3. Do not cover the existing printed text on the tube.
4. Do not apply the label to the cap, to the bag, or to the box.
5. Complete and sign the requisition form, including the collection date and time.
6. Verify that the date and time on the label and the form match.

An unlabeled tube, an undated label, or a mismatch between the tube and the form requires the laboratory to reject the specimen. You would then need to collect again with a new kit.

6 — PACKAGING AND RETURN

1. Place the labeled tube into the biohazard specimen bag.
2. Place the absorbent sheet in the same bag, beside the tube.
3. Seal the bag completely along the adhesive strip.
4. Fold the requisition form and place it in the outer pocket of the bag, **not inside the sealed compartment with the tube**.
5. Place the sealed bag into the prepaid return mailer.
6. Close and seal the mailer.
7. Ship the same day you collect, using the drop-off method described on the mailer.

7 — STORAGE AND TIMING

CONDITION	REQUIREMENT
Before collection	Store the kit at room temperature, 15–30 °C, away from sunlight
After collection, before shipping	Room temperature. Do not refrigerate or freeze.
Ship within	Same calendar day as collection
Maximum transit time	72 hours from collection
Do not ship	On a day the carrier does not collect, or immediately before a holiday

A specimen that exceeds the maximum transit time may not produce a reportable result.

8 — TROUBLESHOOTING

SITUATION	WHAT TO DO	CAN YOU CONTINUE?
The tube leaked before collection	Do not use. Call kit support for a replacement kit.	No
You dropped the collection device	Do not use it. Call kit support for a replacement kit.	No
You could not collect enough	Do not attempt a second collection with the same device. Call kit support.	No
You wrote the wrong date on the label	Do not scratch it out. Call kit support before shipping.	Call first
You forgot to include the requisition form	Call kit support with your kit barcode immediately.	Call first
You missed the same-day shipping window	Call kit support. Do not ship a specimen that has exceeded the transit limit.	Call first
The preservative contacted your skin	Rinse with water. Call kit support and seek medical attention if irritation continues.	Call first

9 — SYMBOLS USED ON THIS KIT

IFU	Consult the instructions for use
LOT	Batch code
REF	Catalog number
EXP	Use by date
15–30 °C	Temperature limit
2	Do not reuse — single use only
☼	Biological hazard

10 — RESULTS AND QUESTIONS

- Results are released through the ordering clinician or the result portal described in your order confirmation.
- This kit does not produce a result at home and does not display anything.
- Questions about what a result means must be directed to your clinician, not to kit support.
- Kit support can help with components, shipping, labeling, and kit status only.

Printed labeling controls: Keep this Instructions for Use. If the printed instruction on your kit differs from any video, web page, or other material, the printed instruction for your kit revision controls.

FICTIONAL SPECIMEN. ClearPath Diagnostics, catalog number CPD-HC-2200, revision DEMO-1, the laboratory identifier, the support numbers, and every procedural detail here are invented for demonstration only. This is not a real Instructions for Use, not approved or cleared labeling for any product, and must never be used to collect a real specimen.