

INTENDED USE

The simpli-COLLECT™ Urine Collection Kit is intended for the self-collection and transport of urine for in vitro diagnostic testing. Urine may be collected and prepared for transport in a healthcare or non-healthcare environment by a lay user.

LIMITATIONS OF THE PROCEDURE

This kit should only be used to collect urine specimens.

WASTE COLLECTION GUIDELINES: PAPER COLLECTION AND PLASTIC COLLECTION		
Packaging Material	Symbol	Definition
Return Box and Outer Wrap		Mixed Paper
Tube and Cap Holder		Polyethylene terephthalate
Sample Tube and Dropper Packaging		Plain Paper and Ethylene-vinyl acetate (EVA)
Instructions for Use		Plain Paper
Mailing Pouch		Low-density polyethylene
Tube and Bag Label Sheet		Plain Paper

Items with the recyclable symbol can be recycled. Follow your national, regional, and local ordinances accordingly for waste disposal regulations.

KEY TO SYMBOLS	
	Exclamation Mark
	In Vitro Diagnostic Medical Device
	In Vitro Test
	Reference Number
	Do Not Re-use
	Temperature Limit
	Expiration Date
	Consult Instructions for Use
	Peel Open Here
	Do Not Use If Package Is Damaged and Consult Instructions for Use
	Important Information
	Dropper
	Sample Tube with Liquid Buffer
	Global Trade Item Number
	Produced By
	Lot Number
	Minimum / Maximum Urine Fill Volume
	Biological Risks
	Store At
	Unique Kit Identifier
	Authorized Representative in the European Community/European Union
	Manufacturer

SUMMARY AND EXPLANATION OF THE TEST

The simpli-COLLECT™ Urine Collection Kit allows you to self-collect urine specimens without supervision (e.g., home or other setting outside a clinical setting).

You will collect and transfer the specimen to the sample tube and return it to the laboratory for analysis.

WARNINGS AND PRECAUTIONS

- FOLLOW ALL INSTRUCTIONS** in the Instructions for Use. If you do not follow the instructions, your result may be incorrect.
- Keep out of reach of children under 14 years old.
- DO NOT USE** the simpli-COLLECT™ Urine Collection Kit if the kit is damaged, the kit box is open, or if the kit is leaking. **DISCARD UNUSED, DAMAGED, OR LEAKING KITS** in accordance with national, regional, and local ordinances.
- DO NOT USE** the simpli-COLLECT Urine Collection Kit if the kit is beyond its **EXPIRATION DATE**.
- The sample tube with liquid buffer contains detergent.** The liquid in the tube may cause serious eye irritation and mild skin irritation. If the liquid comes in contact with your eyes or skin, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do, and continue rinsing. If irritation continues, seek medical advice. **WARNING:** Causes mild skin irritation. Causes serious eye irritation.
- Do not ingest.
- Avoid contact with skin and eyes.

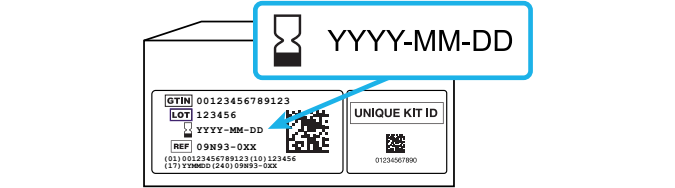
STORAGE

Store kit at room temperature (between 15°C to 30°C or 59°F to 86°F). Ensure all test components are at room temperature before use.

After collection, store sample at room temperature (between 15°C to 30°C or 59°F to 86°F).

EXPIRATION DATE

DO NOT USE the simpli-COLLECT™ Urine Collection Kit if the kit is beyond its **EXPIRATION DATE**.



TECHNICAL ASSISTANCE

Contact your healthcare provider with questions regarding return shipping, test results/diagnosis, or assistance with obtaining a new kit.

If you need support on how to use or store this product please visit:

www.molecular.abbott/int/en/home/simpli-collect



SAFETY PRECAUTIONS

IVD For In Vitro Diagnostic Use

The following warnings and precautions apply to: Sample Tube with Liquid Buffer	
	Warning
H319	Causes serious eye irritation.
H316	Causes mild skin irritation.*
Prevention	
P264	Wash hands thoroughly after handling.
Response	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313	If skin irritation occurs: Get medical advice/attention.*
P337+P313	If eye irritation persists: Get medical advice/attention.

*Not applicable where regulation EC 1272/2008 (CLP) has been implemented.

Safety Data Sheets are available at:
www.molecular.abbott/int/en/home/simpli-collect

Abbott Sample Collection is manufactured for Abbott Molecular Inc. by MML Diagnostics Packaging, Inc., Troutdale, OR 97060 USA.

Abbott Molecular Inc. is the legal manufacturer of the simpli-COLLECT Urine Collection Kit.

The simpli-COLLECT™ Urine Collection Kit is imported into the European Union by Abbott Diagnostics GmbH, located at Max-Planck-Ring 2, 65205 Wiesbaden, Germany.

Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines, IL 60018 USA

EC REP Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden, Germany

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All other trademarks are property of their respective owners.



Read all instructions before you start.
Keep the box. You will use it to send back your sample.



simpli-COLLECT™

Urine Collection Kit
Instructions for Use

Need help? Scan here:



www.molecular.abbott/int/en/home/simpli-collect

en
REF 09N93-005
and higher
53-608478/R2

YOU AND YOUR HEALTH COME FIRST,
SO LET'S GET STARTED!

[More information on other side of page](#)



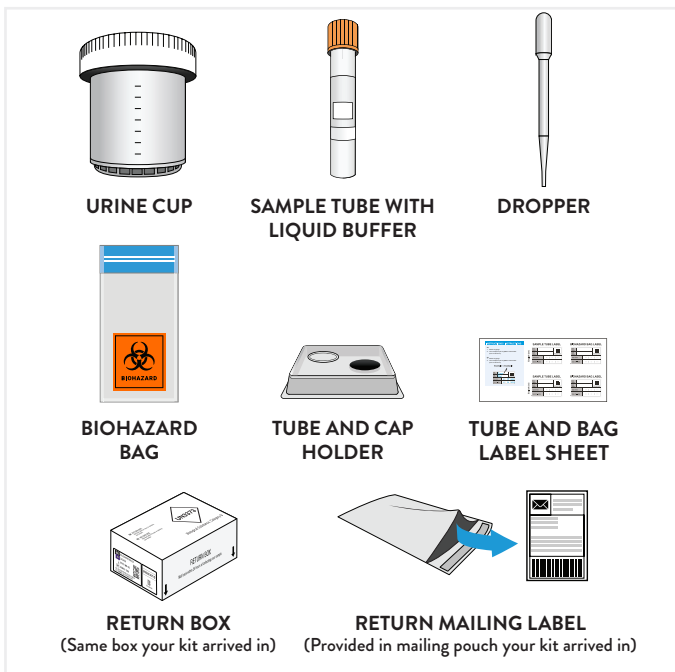
Need help? Scan here.

www.molecular.abbott/int/en/home/simpli-collect

UNPACKING YOUR KIT

- Read and understand the instructions before using the kit. **If you do not follow the instructions, your result may be incorrect.**
- Store kit at room temperature (between 15°C to 30°C or 59°F to 86°F) before and after sample collection.
- Do not use if box arrived unsealed or if parts are missing or damaged.** Contact your healthcare provider for a new kit.
- Unpack kit on a clean, dry surface.
- The liquid in the tube can cause irritation if it comes into contact with your eyes or skin. Read the warning section on the back of these instructions.
- For questions about this kit, read the Technical Assistance section on the back of these instructions.

KIT CONTENTS



BEFORE STARTING

Read and understand the instructions before using the kit.

If you do not follow the instructions, your result may be incorrect.



Make sure you can mail your sample within 24 hours.



Do not urinate for at least one hour before collecting your sample.



Do not clean genital area immediately before collecting sample.



Make sure you use the kit before the **Expiration Date**.

1 SETTING UP



Wash and dry your hands.

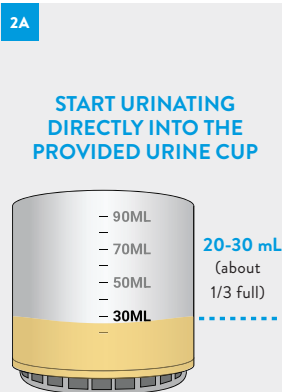
Do not use hand sanitizer.

2 COLLECTING YOUR SAMPLE

Let's begin! Don't worry, it's easy!

For this step, you will need:

- Urine Cup



Do not clean genital area before collecting urine.

Wait at least **one hour** after you last urinated before collecting urine.

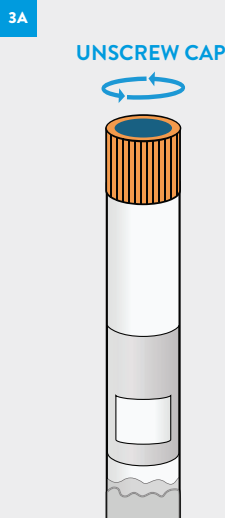
Collect only the first part of the urine (initial stream). Do not start collecting mid-stream.

Fill the urine cup with 20-30 mL of urine (about 1/3 full).

3 TRANSFERRING SAMPLE TO TUBE

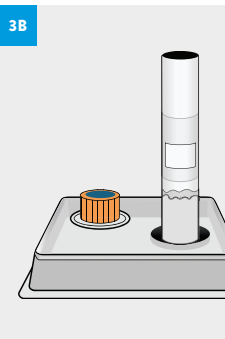
For this step, you will need:

- Your collected urine
- Dropper
- Tube (Sample Tube with Liquid Buffer)
- Tube and Cap Holder



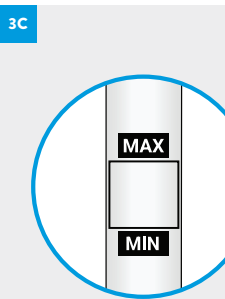
Hold tube upright and unscrew the cap.

- The tube contains liquid! **Do not remove any liquid from this tube.**
- If your tube has leaked, shows signs of leaking (such as dried powder around the cap), or liquid is spilled, contact your healthcare provider to order a new kit.



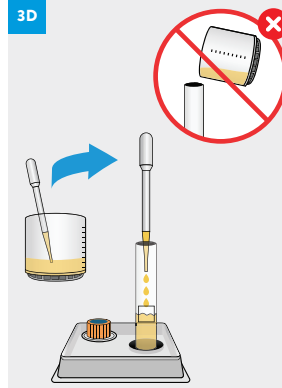
Find the tube and cap holder.

Put the cap within the raised circle and the tube upright in the hole.



Look for the fill window on the side of the tube.

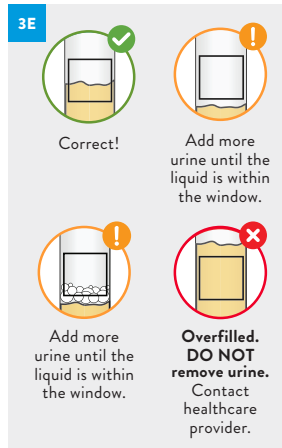
When you transfer urine to the tube, it is important that the liquid level is between the MIN and MAX lines.



Use the dropper to transfer urine from the cup to the tube.

Do not pour directly from the cup. Add drops slowly until the liquid level is within the window.

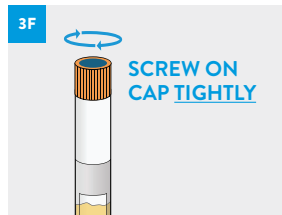
Careful! It's easy to overfill the tube!



Check: Did you fill the tube to the right level?

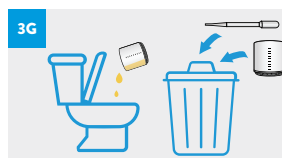
There may be bubbles on the liquid. The top of bubbles do not count as the top of the liquid.

If overfilled (above the window), **do not remove urine from the tube or your result could be incorrect.** Contact your healthcare provider for further instructions.



Hold tube upright and recap the tube by screwing the cap clockwise.

When you feel resistance, keep turning about another quarter turn until cap no longer moves.



Pour any urine remaining in the urine cup into the toilet.

Throw away used urine cup and dropper.

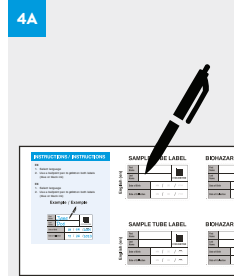


Wash and dry your hands.

4 COMPLETING LABEL INFORMATION

For this step, you will need:

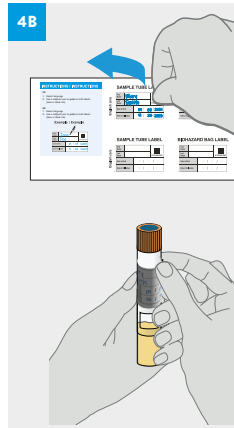
- Ballpoint pen (blue or black ink - not provided)
- Tube (containing urine)
- Biohazard bag
- Tube and bag label sheet



Locate the sample tube label and biohazard bag label in your language.

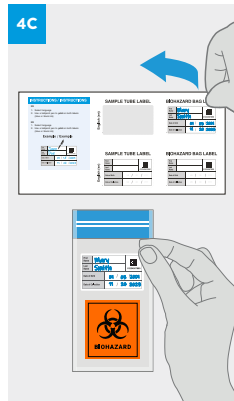
Use a ballpoint pen to **print** on both labels. Fill out **both** labels with:

- First Name
- Last Name
- Date of Birth
- Date of Collection



Peel the **sample tube label** off the label sheet and stick it on the **sample tube**.

Do not cover the fill window with the label.



Peel the **biohazard bag label** off the label sheet and stick it on the **biohazard bag**.

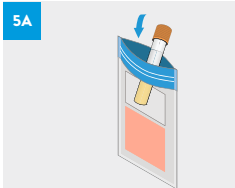
Do not cover the biohazard symbol.

You may not receive your results if the labels are not filled out correctly!

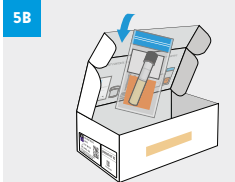
5 RETURNING SAMPLE

For this step, you will need:

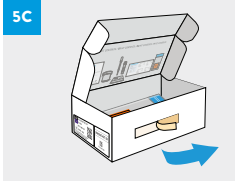
- Return mailing label (provided in mailing pouch)
- Tube (containing urine)
- Biohazard bag
- Return box



Put the tube in the biohazard bag. Seal the bag completely.



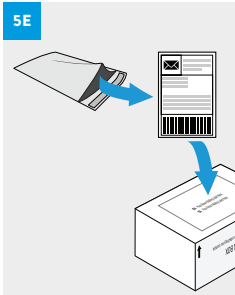
Put the biohazard bag (containing your tube) into the return box.



Peel the self-adhesive tape on box and close the lid to seal the box.



Flip the box over.



Find the return mailing label in the mailing pouch your kit arrived in.

Stick the return mailing label on the bottom of the return box — **do not** cover UN3373 label!

Mail your sample to the laboratory within 24 hours.

CONGRATULATIONS! You've finished your part. Now your sample will travel to the laboratory and be tested. Talk to your healthcare provider about your results.

