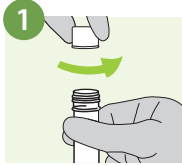


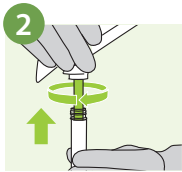


User instructions:

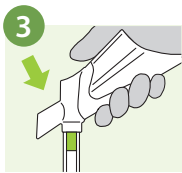
Do NOT wash your genitals before urinating. Wash hands before and after sample collection. Ensure you have a full bladder; do not urinate 1 hour prior to use. Keep the box. You will use it to send back your sample.



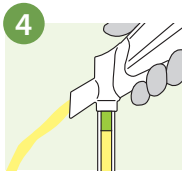
Unscrew the cap from the tube. Do not discard the cap.



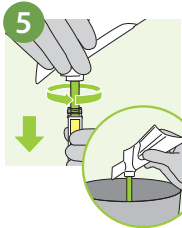
Attach the Colli-Pee™-Dx device funnel on to the tube.



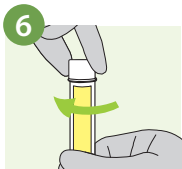
Position the Colli-Pee™-Dx device funnel in front of the genitals with the spout aimed at the toilet.



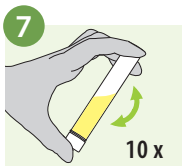
Begin urinating. The Colli-Pee™-Dx device will automatically collect the correct amount of urine. There is no need to stop urine flow during collection. Any extra urine will go into the toilet.



Holding the Colli-Pee™-Dx device upright, remove the funnel from the tube. Discard the Colli-Pee™-Dx device funnel.



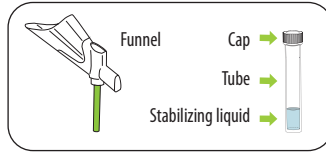
Put the cap back on the tube tightly to prevent leakage.



Invert the tube 10 times to mix.

ENGLISH
User instructions

REF N00399M 4 mL



Read all instructions prior to collection.

Intended use: The Colli-Pee™-Dx Urine Collection Kit is a device for the self-collection of first-void urine for the purpose of collecting and transporting specimens for use in an FDA cleared STI molecular assay with which the device has been validated. The Colli-Pee™-Dx Urine Collection Kit can be used in both at-home and in any private setting.

Contents: The Colli-Pee™-Dx Urine Collection Kit consists of:

- Colli-Pee™-Dx device
 - › Funnel
 - › Specimen tube and cap with 0.67 mL of stabilizing liquid
 - › Instructions for use
- Bubble bag
- Bio-specimen bag
- Return instructions card
- Mailer box
- Mailing materials (supplied by the test provider)

Kit storage: 15°C † 30°C (59°F † 86°F)

Warnings and precautions:

- FOR EXTERNAL USE ONLY.
- For In Vitro Diagnostic Use only.
- Rx Only.
- Follow all instructions in the instructions for use. If you do not follow the instructions, your result could be incorrect.
- Do not use the Colli-Pee™-Dx Urine Collection Kit if past the use by date, damaged, or is missing parts.
 - › Mail your specimen within 24 hours of collection.
- The Colli-Pee™-Dx Urine Collection Kit does not give you an immediate result. Follow the instructions provided in the return mailer box to collect and send your specimen to the laboratory for testing.
- Do NOT wash your genitals before urinating.
- Wash hands before and after specimen collection.
- Ensure you have a full bladder; do not urinate 1 hour prior to use.
- Hold the tube upright when uncapped to avoid spillage. If spillage occurs, request a replacement kit.
- Do not touch or drink the stabilizing liquid. Wash with water if stabilizing liquid comes in contact with eyes or skin.
- See the safety data sheet for the Colli-Pee™-Dx Urine Collection Kit at www.dnagenotek.com/ed/index#sds-colli-pee.
- Small cap may pose a choking hazard.
- Report any serious incident to DNA Genotek Inc. and the competent authority in your country.
- If you have trouble using any items inside the box or understanding the instructions, contact your healthcare provider.

Limitations

1. The Colli-Pee™-Dx Urine Collection Kit is only intended to be used with the Roche cobas® CT/NG and cobas® TV/MG assays on cobas® 5800/6800/8800 systems for STI laboratory testing and is not a substitute for visiting a healthcare provider.
2. Specimen quality is dependent on adherence to the instructions for collection, shipping and storage specifications, and failure to follow these instructions can lead to incorrect test results.

Performance

The clinical study and equivalence study data demonstrate performance of the Colli-Pee™-Dx Urine Collection Kit is comparable with the FDA cleared on-label urine collection kit for use with the Roche cobas® CT/NG and cobas® TV/MG assays.

After collecting the urine specimen, follow the directions on the return instructions card to mail the specimen to the laboratory for testing. **Specimens should be mailed within 24 hours of collection.** The sample does not need to be frozen or refrigerated.

For more information on the Colli-Pee™-Dx Urine Collection Kit, scan the QR code to refer to the Colli-Pee™-Dx product handbook and frequently asked questions (FAQs) or visit us at dnagenotek.com/collipee-dx.



Label legend:

	Catalog number
	In vitro diagnostic use
	Prescription use only
	Do not use if package is damaged
	Manufacturer
	Do not reuse
	Consult instructions for use
	Use by
	Lot number
	Storage instructions
	15°C † 30°C 59°F † 86°F

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