Urine Collection Kit

COLLI-pee™-Dx

Product handbook

REF N00399M

DNAgenotek™

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IVD

Rx ONLY

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The Colli-Pee™•Dx Urine Collection Kit is an In Vitro Diagnostic Use and Prescription Only (Rx only) kit

Intended use

The Colli-Pee™•Dx Urine Collection Kit is 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. Colli-Pee™•Dx Urine Collection Kit can be used at-home or in any private setting.

Product description

The Colli-Pee™•Dx Urine Collection Kit is a first-void urine collection kit designed for use in sexually transmitted infection (STI) testing. The Colli-Pee™•Dx Urine Collection Kit enables the standardized, volumetric collection of first-void urine and specimen stabilization that is powered by the proprietary NucleoPrecision™ technology for use both at-home and in any private setting. Collected specimens are mailed to a laboratory for analysis.

In the laboratory, the urine specimen is tested using an FDA cleared sexually transmitted infection (STI) molecular assay with which the kit has been validated. The Colli-Pee™•Dx Urine Collection Kit has been validated with the Roche cobas® CT/NG and cobas® TV/MG assays.

The Colli-Pee™•Dx Urine Collection Kit is single use and must be prescribed by a medical provider. The Colli-Pee™•Dx Urine Collection Kit is indicated solely for STI testing and must not be used for any other diagnostic purposes.

Features of the Colli-Pee™•Dx Urine Collection Kit

- Non-invasive and reliable for the collection of volumetric first-void urine.
- Transportable for 5 days with no temperature controls.
- Collected specimens remain stable if stored at 2°C to 30°C/36°F to 86°F for 30 days post-transportation.
- Collected specimens are suitable for STI testing using FDA cleared STI molecular assays that have been validated with the Colli-Pee™•Dx Urine Collection Kit.
- 1D barcode tracking to improve workflow efficiency and specimen traceability.

Colli-Pee™•Dx Urine Collection Kit materials

The Colli-Pee™•Dx Urine Collection Kit (Figure 1) contains:

- 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)

Figure 1. Representative image of the Colli-Pee™•Dx Urine Collection Kit.

Warnings and precautions

- General 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.
  - 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.*
    **Mail your specimen within 24 hours of collection.*

- Specimen collection warnings and precautions:
  - 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/collipee-dx-sds.
  - 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

- Laboratory warnings and precautions:
  - Interference was observed with cobas CT/NG when protein above 0.5% (w/v) and blood above 1% (w/v) were tested. For additional relevant interfering substances, refer to cobas CT/NG and cobas TV/MG assay procedural limitations.
  - Decontaminate and dispose of all specimens, reagents and other potentially contaminated materials in accordance with local, state and federal regulations
  - See the safety data sheet for the Colli-Pee™•Dx Urine Collection Kit at www.dnagenotek.com/collipee-dx-sds.
  - Refer to the procedural limitations in the Roche cobas® TV/MG assay instructions and follow the intended use population age limitation.

Summary and explanation of the Colli-Pee™•Dx Urine Collection Kit

The Colli-Pee™•Dx Urine Collection Kit enables the standardized, volumetric collection of first-void urine both at-home and in any private setting.

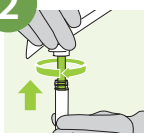
To collect first-void urine using the Colli-Pee™•Dx Urine Collection Kit, locate the Colli-Pee™•Dx device in the box, open the pouch, attach the funnel to the tube and position it for collection. The device automatically captures the first-void urine, while excess urine flows safely into the toilet. The device ensures the correct volume is collected without the user needing to stop or start the flow of urine. After urination, the funnel is removed and discarded, the tube is sealed with a cap and inverted manually by the user 10 times to mix the specimen with stabilizing liquid. The collected specimen is mailed back to the laboratory using the mailer box.

Collection instructions

1

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

2

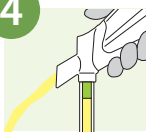


Attach the Colli-Pee™•Dx device funnel on to the tube.

3

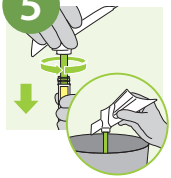
Position the Colli-Pee™•Dx device funnel in front of the genitals with the spout aimed at the toilet.

4



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.

5



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

6

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

7

Invert the tube 10 times to mix.

Instructions for urine collection using the Colli-Pee™•Dx Urine Collection Kit are provided with the kit and can be found at dnagenotek.com/collipee-dx-ifu.

Instructions for returning the urine specimen to the laboratory using the return mailer box are provided with the kit and can be found at dnagenotek.com/collipee-dx-rmb.

The Colli-Pee™•Dx Urine Collection Kit mailing workflow

- To ship all materials required for at-home collection using the Colli-Pee™•Dx Urine Collection Kit, the laboratory should place the Colli-Pee™•Dx Urine Collection Kit and the prepaid return mailing label in a protective mailing pouch. Apply the outbound mailing label to the pouch. All applicable shipping regulations must be followed.
- After collecting the urine specimen, the user should follow the directions on the return card to mail the specimen to the laboratory for testing.*
  **Specimen should be mailed within 24 hours of collection.*
- Urine specimens will arrive at the laboratory in the provided mailer box via postal services.

Transport of the Colli-Pee™•Dx Urine Collection Kit

The Colli-Pee™•Dx Urine Collection Kit has been validated during expected transport conditions to support the at-home self-collection of a first-void urine specimen when used for STI testing.

Post-collection

Specimens should be shipped to the testing laboratory within 24 hours of collection. The specimen does not need to be frozen or refrigerated.

Laboratory processing instructions

- Patient details and collection date are located on the inside of the mailer box lid.
- Do not process specimens received 5 days after collection.
- Do not use specimens if the tube is damaged, or if there is insufficient specimen volume for testing.
- Transfer the full volume of the Colli-Pee™•Dx device specimen tube to a Roche cobas® assay-compatible secondary tube.

- To continue with specimen processing, refer to the Roche cobas® CT/NG and/or cobas® TV/MG assay instructions for detailed and up-to-date procedures.

Storage of the Colli-Pee™•Dx Urine Collection Kit

Pre-collection

- Store the Colli-Pee™•Dx Urine Collection Kit at 15°C to 30°C/59°F to 86°F for 12 months.

Post-collection

- Specimens collected with the Colli-Pee™•Dx Urine Collection Kit provide first-void urine specimens suitable for STI testing on the Roche cobas® CT/NG and cobas® TV/MG assays.
- Specimens collected with the Colli-Pee™•Dx Urine Collection Kit can be stored at ambient temperature (2°C to 30°C/36°F to 86°F) for 30 days after transport to the laboratory.

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 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.

Non-clinical performance characteristics

Precision

A precision study was conducted using three lots of the Colli-Pee™•Dx Urine Collection Kit. Negative male and female urine matrix co-spiked with *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) was added to Colli-Pee™•Dx devices. Samples were spiked at concentrations representative of low- and high-positive samples. Analyte-negative male and female urine samples were also included. All samples tested using the cobas® CT/NG assay produced the expected results at baseline and following test conditions.

Shelf-life stability

The Colli-Pee™•Dx Urine Collection Kits underwent stability testing following exposure to real-time aging conditions to support a shelf life of 12 months. For real-time aging, the Colli-Pee™•Dx Urine Collection Kits were stored at temperatures flanking the labeled storage temperature of 15°C to 30°C/59°F to 86°F. At each study time point, functional (cobas® CT/NG and cobas® TV/MG assays), chemical and physical (pH, Refractive Index, chemistry visual inspection, evaporation and visual inspection of plastics/labels/pouch) endpoints were evaluated in three (3) lots of devices at baseline and following exposure to the various test conditions. For functional performance testing, male and female negative urine matrix co-spiked CT and NG or *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG) at concentrations representative of low-positive samples and analyte-negative samples were added to the aged Colli-Pee™•Dx Urine Collection Kits and tested. A subset of Urine Collection Kits containing co-spiked urine samples were subsequently stored at 32°C for 33 days to evaluate stability of the microorganisms in the aged devices. Study results showed that the Colli-Pee™•Dx Urine Collection Kits performed as expected, with the results supporting a shelf life of 12 months.

Sample stability

A sample stability study was conducted using replicates of analyte-negative male and female urine samples and positive samples (male and female negative urine matrix co-spiked with either CT and NG or TV and MG at concentrations representative of low-positive and/or high-positive samples). The study evaluated the Colli-Pee™•Dx Urine Collection Kit performance for sample shipping and laboratory storage stability under the following test conditions:

- Simulated summer and winter transport profile cycling conditions (-10°C to 40°C/14°F to 104°F) representing extreme cold and hot temperatures for durations anticipated during a 130-hour (5-day) shipping period from the time of sample collection to receipt at the testing laboratory.
- Simulated summer and winter transport followed by 30 days of storage in the laboratory at temperatures (2°C to 30°C/36°F to 86°F).

At the study timepoints, both positive and negative sample in multiple replicates were tested with cobas® CT/NG and/or cobas® TV/MG assays. Expected results were obtained for all negative and positive samples at all conditions.

Detection limit

The Limit of Detection (LoD) for CT, NG, TV and MG was determined using representative target microorganisms in pooled negative male and female urine, collected in Colli-Pee™•Dx Urine Collection Kit and then tested with the cobas® CT/NG and cobas® TV/MG assays, respectively. For the preliminary LoD, five independent replicates were co-spiked with either CT/NG or TV/MG across a range of five concentrations. The LoD was confirmed by testing 20 replicates at the preliminary LoD for each microorganism to determine the concentration that gave positive test results in ≥ 95% of the samples (at least 19/20 replicates testing positive for each strain). Results are shown in Table 2.

Table 2. LoD of CT, NG, TV and MG in negative clinical urine matrix

Colli-Pee™•Dx	CT	NG	TV	MG
Male	10 IFU/mL	0.25 CFU/mL	0.5 cells/mL	3 cp/mL
Female	2 IFU/mL	0.25 CFU/mL	0.5 cells/mL	3 cp/mL

Interfering substances

A study was performed to evaluate whether relevant endogenous and exogenous substances, including substances commonly used by lay users at home or in any private settings may interfere with the detection of CT, NG, TV and MG using Colli-Pee™•Dx Urine Collection Kit samples. Both positive and negative urine samples were tested with and without the potential interfering substances. The positive samples were prepared using male and female negative urine matrix co-spiked with low concentrations of CT and NG or TV and MG. Substances tested are described in Tables 3 and 4. The indicated concentrations represent the tested concentration of a substance, when assessed with the cobas® CT/NG and cobas® TV/MG assays, that did not result in interference. For additional interfering substance study data, refer to K173887 and K190433.

Table 3. Interfering substances study results with cobas® CT/NG assay.

Test substance	Concentration without interference
Low pH	4
High pH	9
Protein	0.5% (w/v)*
Blood	1% (w/v)*
Mucus	0.5% (w/v)
Summer's Eve Deodorant	0.25% (w/v)
Vagisil Deodorant	0.25% (w/v)
Vagisil Feminine Powder	0.25% (w/v)
Monistat Vaginal Cream	0.25% (w/v)
Vagisil Vaginal Cream	0.25% (w/v)
RepHresh Vaginal Gel	0.25% (w/v)
Gynalac Vaginal Gel	0.25% (w/v)
CeraVe Lotion	0.1% (w/v)
Purell Hand Sanitizer	0.1% (w/v)
Zytec Hand Sanitizer	0.1% (w/v)
Soft Soap Hand Soap	0.001% (w/v)
Dial Hand Soap	0.001% (w/v)
Banana Boat Sunscreen	0.1% (w/v)
Coppertone Sunscreen	0.1% (w/v)
Water	10% (w/v)

*Interference was observed at concentrations above this level

Table 4. Interfering substances study results with cobas® TV/MG assay.

Test substance	Concentration without interference
Low pH	4
High pH	9
Protein	0.5% (w/v)*
Blood	1% (w/v)*
Mucus	0.5% (w/v)
Summer's Eve Deodorant	0.25% (w/v)
Vagisil Deodorant	0.25% (w/v)
Vagisil Feminine Powder	0.25% (w/v)
Monistat Vaginal Cream	0.25% (w/v)
Vagisil Vaginal Cream	0.25% (w/v)
RepHresh Vaginal Gel	0.25% (w/v)
Gynalac Vaginal Gel	0.25% (w/v)
CeraVe Lotion	0.1% (w/v)
Purell Hand Sanitizer	0.1% (w/v)
Zytec Hand Sanitizer	0.1% (w/v)
Soft Soap Hand Soap	0.001% (w/v)
Dial Hand Soap	0.001% (w/v)
Banana Boat Sunscreen	0.1% (w/v)
Coppertone Sunscreen	0.1% (w/v)
Water	10% (w/v)

Colli-Pee™•Dx Urine Collection Kit robustness

To demonstrate Colli-Pee•Dx Urine Collection Kit robustness, kits were challenged under the following conditions and low-positive and negative samples were tested with cobas® CT/NG or cobas® TV/MG assays:

- Urine collection volume variability
- Insufficient mixing of the specimen with stabilizing liquid

Across all testing conditions, expected results were obtained.

To demonstrate that Colli-Pee™•Dx Urine Collection Kit can withstand shipping without affecting product integrity, the kits were challenged and tested in accordance with ASTM D4169 standard testing, and the packages and components within the kit were inspected for damage after challenge. After undergoing drop, compression, and vibration testing no damage was found, with the results demonstrating the mechanical robustness of the Colli-Pee™•Dx Urine Collection Kit.

Usability and user comprehension

Device usability and user comprehension was assessed to demonstrate the safety and effectiveness of the Colli-Pee™•Dx Urine Collection Kit for the at-home self-collection of first-void urine. The study was designed to simulate a workflow of the at-home self-collection of urine for testing on the cobas® CT/NG and cobas® TV/MG assays. Users were mailed the Colli-Pee™•Dx Urine Collection Kit, instructed to self-collect a urine specimen and mail the sample back to a testing laboratory. The study population of 219 naïve users included male and female participants ages 14 years and older, across different education levels and demographic groups representative of the U.S. general population. Usability study results demonstrated high user comprehension and ability to execute procedural steps across study participants.

Hazard analysis and mitigations

A comprehensive hazard analysis of the Colli-Pee™•Dx Urine Collection Kit was conducted in accordance with ISO 14971:2019, to identify known and foreseeable hazards and hazardous situations and ensure that their risks are appropriately assessed and controlled when used under the conditions of intended use. Specific risks associated with human factors, sample and device handling, storage, and environmental factors were evaluated. Risk control measures have been implemented to reduce the risks.

Frequently asked questions

A Frequently Asked Questions (FAQs) section has been included for lay users to provide educational information regarding the safety, benefit, and precautions of self-collection.

Biocompatibility

Biocompatibility risk assessment for the different housing components for the Colli-Pee™•Dx Urine Collection Kit and chemical toxicity assessment evaluating the worst-case exposure of the chemicals in the stabilizing liquid was conducted and yielded acceptable results.

Clinical performance characteristics

Clinical studies

The clinical performance of the Colli-Pee™•Dx Urine Collection Kit is supported by the following datasets:

The clinical performance for male and female urine was established in K173887 and K190433 and data were leveraged based on the established equivalence.

A separate prospective clinical study was conducted, enrolling female participants, to support the performance of the Colli-Pee™•Dx Urine Collection Kit for use with cobas® CT/NG and cobas® TV/MG assays. Female participants (n = 1357) were enrolled at 11 enrollment sites across the U.S. between November 3, 2025, and April 9, 2026. Each participant self-collected three specimens in simulated home environment following respective instructions for use: a urine specimen collected using the FDA cleared on-label urine collection kit, a urine specimen collected using the Colli-Pee™•Dx Urine Collection Kit, and a vaginal swab specimen collected using the FDA cleared on-label kit. All specimens were tested per cobas® CT/NG and cobas® TV/MG assay instructions. The Colli-Pee™•Dx Urine Collection Kit performance was calculated by comparing each urine collection device result to the paired vaginal swab result to determine the ratios (Colli-Pee™•Dx Urine Collection Kit: on-label urine collection kit) of Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA). The performance for each analyte is summarized in Table 5.

Table 5. Ratios of agreement with the vaginal swab specimens for the Colli-Pee™•Dx Urine Collection Kit as compared to the FDA cleared on-label urine collection kit.

Target Analyte	Ratio of Positive Percent Agreement (PPA)	Ratio of Negative Percent Agreement (NPA)
CT	1.027 (95% CI: 0.973, 1.081)	1.000 (95% CI: 0.998, 1.002)
NG	0.947 (95% CI: 0.847, 1.048)	1.000 (95% CI: N/A*)
TV	1.046 (95% CI: 0.993, 1.100)	0.998 (95% CI: 0.992, 1.004)
MG	1.103 (95% CI: 0.980, 1.226)	1.004 (95% CI: 0.998, 1.010)

*95% CI by normal approximation is not available.

Troubleshooting

Laboratory processing

Observation	Action
Specimen tube is leaking upon arrival at processing laboratory.	Discard specimen. Do not use the specimen for testing and instruct the user to re-collect specimen.
Specimen is frozen.	Allow specimen to thaw by incubating at room temperature for at least 1 hour. Invert specimen 10x prior to proceeding with specimen processing steps.
Specimen is received after 5 days of collection.	Discard specimen. Do not use the specimen for testing and instruct the user to re-collect specimen.

Label legend

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

Technical support is available Monday to Friday (9h00 to 17h00 ET):

- Toll-free (North America): 1.866.813.6354, option 6
- All other countries: +1.613.723.5757, option 6
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For In Vitro Diagnostic Use