

Xpert[®] Urine Specimen Collection Kit

REF URINE/A-50

Instructions for Use

IVD CE

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See Section 14, Revision History for a description of changes.

Xpert® Urine Specimen Collection Kit

For *In Vitro* Diagnostic Use only.



1 Proprietary Name

Xpert® Urine Specimen Collection Kit

2 Common or Usual Name

Xpert Urine Specimen Collection Kit

3 Intended Purpose

3.1 Intended Use

The Xpert® Urine Specimen Collection Kit is designed to preserve and transport *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA in first-catch female and male urine specimens from symptomatic and asymptomatic individuals prior to analysis with the Xpert CT/NG test and the Xpert TV test.

3.2 Intended User/Environment

The Xpert Urine Specimen Collection Kit is intended to be used by trained users.

4 Summary and Explanation

Refer to the Instructions for Use for the Xpert CT/NG test or the Xpert TV test (as appropriate).

5 Principle of the Procedure

The Xpert Urine Specimen Collection Kit allows for an extended range of time and temperature conditions for specimen storage and transport when testing for the presence of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, or *Trichomonas vaginalis* in urine specimens using the Xpert CT/NG test or the Xpert TV test (as appropriate). Approximately 7 mL of first-catch urine is transferred from the collection cup to the Xpert Urine Transport Reagent tube using a disposable transfer pipette.

Please refer to the Pictorial Instructions for Use (301-5611).

6 Reagents

6.1 Materials Provided

Xpert Urine Specimen Collection Kits (quantity: 50)

Xpert Urine Specimen Collection Kits are packaged in quantities of 50, therefore each kit box contains sufficient reagents to process 50 urine specimens. Each Xpert Urine Specimen Collection Kit is individually contained within a sealed package. Quantities are as follows:

- 1 Instructions for Use per box of 50 kits
- 1 laminated urine specimen collection sheet per box of 50 kits
- 1 individually wrapped sterile disposable transfer pipette
- 1 capped tube containing Xpert Urine Transport Reagent (yellow cap, Contains Ammonium Chloride and Potassium Carbonate)

Note Safety Data Sheets (SDS) are available at www.cepheid.com or <https://www.cepheidinternational.com> under the SUPPORT tab.

7 Materials Required but Not Provided

- Clean, plastic, preservative-free, urine collection cups
- Disposable gloves
- Adhesive labels or sample identification information
- Xpert CT/NG test or the Xpert TV test

8 Warnings, Precautions, and Chemical Hazards

8.1 Warnings and Precautions

- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be treated with standard precautions. Guidelines for specimen handling are available from the U.S. Center for Disease Control and Prevention and the Clinical and Laboratory Standards Institute.^{1,2}
- Good laboratory practices should be followed, and gloves should be changed between handling each patient specimen in order to avoid contamination of specimens or reagents. Regularly clean the work surface/areas.
- Do not use Xpert Urine Specimen Collection kits that have passed the expiration date.
- Avoid cross contamination during sample handling steps.
- Do not use kit if opened or damaged.
- Spilled or leaking transport reagent tubes should be discarded and not used.
- A single-use disposable transfer pipette is used to transfer one specimen. Do not reuse disposable transfer pipettes.
- Wear protective disposable gloves, laboratory coats and eye protection when handling specimens and reagents. Wash hands thoroughly after handling specimens and test reagents.
- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- Use this collection kit only with the Xpert CT/NG Assay or the Xpert TV Assay.
- With urine specimens tested with the Xpert CT/NG test, assay interference may be observed in the presence of: blood (>0.3% v/v), mucin (>0.2% w/v), bilirubin (>0.2 mg/mL), or Vagisil feminine powder (>0.2% w/v).

8.2 Chemical Hazards³

- **Signal Word: Warning**
- **UN GHS Hazard Pictogram:** 
- **UN GHS Hazard Statements**
 - Causes serious eye irritation
- **Precautionary Statements**
 - **Prevention**
 - Wash thoroughly after handling.
 - Wear protective gloves/protective clothing/eye protection/face protection.
 - **Response**

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- If eye irritation persists: Get medical advice/attention.

9 Specimen Collection, Transport, and Storage

9.1 Specimen Collection

1. The patient should not have urinated for at least 1 hour prior to specimen collection.

Female patients should not cleanse the labial area prior to collecting the specimen. Male patients should not cleanse the tip of the penis prior to collecting specimen.

2. Direct patient to provide first-catch urine (approximately 20 to 50 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.
3. Ensure that the urine is well mixed in the urine cup before transferring a sample to the Xpert Urine Transport Reagent tube.
4. Open the packaging of a disposable transfer pipette provided in the kit.
5. Remove the cap from the Xpert Urine Transport Reagent tube and from the urine collection cup.
6. Insert the transfer pipette into the urine cup so that the tip is near the bottom of the cup. Transfer approximately 7 mL of urine into the Xpert Urine Transport Reagent tube using the disposable transfer pipette. The correct volume of urine has been added when the level reaches the black dashed line on the label of the Xpert Urine Transport Reagent tube.
7. Replace the cap on the Xpert Urine Transport Reagent tube and tighten securely.
8. Invert the reagent tube 3-4 times to ensure that the specimen and reagent are well mixed.
9. Label the transport tube with sample identification information, including the date of collection, as required. Do not obscure the black-dashed fill line on the Xpert Urine Transport Reagent tube.

9.2 Kit Storage Requirements

- Store collection kit at 2 °C to 30 °C.
- The Xpert Urine Specimen Collection Kit can be stored at 2 °C to 30 °C for 36 months (see expiration date).

9.3 Specimen Stability

Refer to the Instructions for Use for the Xpert CT/NG test or the Xpert TV test (as appropriate).

10 Limitations

Use this collection kit only with the Xpert CT/NG or Xpert TV tests.

11 References

1. Centers for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories (refer to latest edition). www.cdc.gov/biosafety/publications.
2. Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (refer to latest edition).
3. Chemical hazards determined under REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 (on classification, labeling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006) and the Occupational Safety and Health Standards, Hazard Communication, Toxic and Hazard Substances (March 26, 2012) (29 C.F.R., pt. 1910, subpt. Z), can be referenced on the Safety Data Sheet available at www.cepheid.com and www.cepheidinternational.com under the SUPPORT tab.

12 Technical Assistance

Before Contacting Us

Collect the following information before contacting Cepheid Technical Support:

- Product name
- Lot number

United States

Telephone: +1 888 838 3222

Email: techsupport@cepheid.com

France

Telephone: + 33 563 825 319

support@cepheideurope.com

Contact information for all Cepheid Technical Support offices is available on our website: <https://www.cepheid.com/en/CustomerSupport>.

13 Table of Symbols

| Symbol | Meaning |
|---|---|
|  | Catalog number |
|  | <i>In vitro</i> diagnostic medical device |
|  | Do not reuse. |
|  | Batch code |
|  | Consult Instructions for Use |
|  | Caution |
|  | Manufacturer |
|  | Country of Manufacturer |
|  | Control |
|  | Contains sufficient for <i>n</i> tests |
|  | Expiration date |
|  | Ce marking – European Conformity |
|  | Temperature limitation |
|  | Biological risks |

| Symbol | Meaning |
|---|---|
|  | GHS Health Hazard Pictogram - Exclamation |
|  | Authorized Representative in the European Community |



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Switzerland

14 Revision History

Description of Changes: 302-6825 Rev. A

Purpose: To align with the requirements of Regulation (EU) 2017/746 and other applicable updates.

| Section | Description of Changes |
|------------|--|
| Throughout | Instances of "assay" used as a brand name changed to "test". |
| Legal Page | Added Trademark, Patents and Copyright Statement page. |
| 3 | Added Intended Purpose, Intended User/Environment per IVDR requirements. |
| 8 | Added Warning Symbol. Added details to Chemical Hazards section from the Safety Data Sheet (available online). |
| 13 | Added importer details for EU and Switzerland. |
| 14 | Revision history table added. |