GeneXpert
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Xpert® Urine Transport Reagent Kit

REF **GXUTR-CE-30**

Instructions for Use

IVD CE

Cepheid

In Vitro Diagnostic Medical Device

302-6829, Rev. A
July 2022

Trademark, Patents and Copyright Statements

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

Xpert® Urine Transport Reagent Kit

In Vitro Diagnostic Medical Device

1 Proprietary Name

Xpert® Urine Transport Reagent Kit

2 Common or Usual Name

Xpert Urine Transport Reagent Kit

3 Intended Purpose

3.1 Intended Use

The Xpert Urine Transport Reagent Kit is designed to collect, preserve, and transport urine specimens to the laboratory for analysis with the Xpert® Bladder Cancer Monitor and the Xpert® Bladder Cancer Detection tests.

3.2 Intended User/Environment

The Xpert Urine Transport Reagent Kit is intended to be used by trained users.

4 Summary and Explanation

Refer to the instructions for use for the Xpert Bladder Cancer Monitor or Xpert Bladder Cancer Detection tests (as appropriate).

5 Principle of the Procedure

The Xpert Urine Transport Reagent Kit users use a collection device to collect a urine specimen that is not the first void of the day, following the institution's standard procedures.

The following steps take place once the Xpert Urine Transport Reagent Kit is opened by a trained user.

1. Urine specimens must first be treated with the Xpert Urine Transport Reagent Kit containing the preservative Guanidinium chloride solution. The trained user transfers 4.5 mL of voided urine to the Urine Transport Reagent tube within 1 hour of specimen collection.
2. The tube is inverted three times to mix.
3. Urine specimens in the Urine Transport Reagent tubes are stable up to 7 days at 2–28 °C before testing. Trained user may store the specimen or test the specimen on the Xpert Bladder Cancer Monitor or the Xpert Bladder Cancer Detection tests.

Note For further steps of the Bladder Cancer tests, refer to the appropriate Xpert Bladder Cancer Monitor or the Xpert Bladder Cancer Detection Instructions for Use.

6 Reagents

6.1 Materials Provided

The Xpert Urine Transport Reagent Kit box contains sufficient reagents to process 30 urine specimens. Each Xpert Urine Transport Reagent Kit box contains the following:

Xpert Urine Transport Reagent Kit	30 Kits per box
• Urine Transport Reagent tube	1 tube per kit
◦ Guanidinium chloride solution	4.5 mL per tube
• Disposable transfer pipette	1 per kit pouch
• Instructions for Use	1 per box of 30 kits

Note Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the **SUPPORT** tab.

7 Materials Required but not Provided

- Clean, plastic, preservative-free, urine specimen collection cups
- Disposable gloves
- Laboratory coat and eye protection
- Labels and/or indelible labeling marker for sample identification information

8 Warnings, Precautions and Chemical Hazards

8.1 Warnings and Precautions

- Treat all biological specimens 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. Centers for Disease Control and Prevention[1] and the Clinical and Laboratory Standards Institute.[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 Transport Reagent kits that have passed the expiration date.
- Avoid cross contamination during specimen handling steps.
- 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 specimens.
- Consult your institution's environmental waste personnel on proper disposal of unused reagents.
- Biological specimens, transfer devices, and transport containers should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution’s environmental waste procedures for proper disposal of unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures. If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used transport materials should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

8.2 Chemical Hazards

Specimen/Sample Reagent

- Xpert Urine Transport Reagent Kit contains guanidinium chloride which is toxic if swallowed, irritating to the eyes and skin and is harmful to aquatic life.
- See Regulation EC 1272/2008 (EU CLP).

- **UN GHS Hazard Pictogram:** 
- **UN GHS Hazard Statements**
  - Harmful if swallowed
  - Causes skin irritation
  - Causes serious eye irritation
- **Precautionary Statements**
  - **Prevention**
    - Wash thoroughly after handling.
    - Do not eat, drink, or smoke when using this product.
    - Wear protective gloves/protective clothing/eye protection/face protection.
  - **Response**
    - IF ON SKIN: Wash with plenty of soap and water. Specific treatment, see supplemental first aid information. Take off contaminated clothing and wash before reuse. If skin irritation occurs: Get medical advice/attention.
    - 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 SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
  - **Storage/Disposal**
    - Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.
  - **Other Hazards**
    - UN GHS According to the Globally Harmonized System for Classification and Labeling (GHS) this product is considered hazardous

9 Specimen Collection, Transport, and Storage

Specimen Collection

- Follow your institution's protocol for specimen collection.
- Collect urine specimen that is not the first void of the day. Following your institution's standard procedures.

Kit Storage Requirments

- Store the Xpert Urine Transport Reagent Kit at 2 °C – 28 °C.
- The Xpert Urine Transport Reagents kits can be stored at 2 °C – 28 °C for up to 24 months (see expiration date).

Specimen Stability

Refer to the instructions for use for the Xpert Bladder Cancer Monitor or Xpert Bladder Cancer Detection tests (as appropriate).

10 Procedure

Note Do not use Xpert Urine Transport Reagent Kits that have passed the expiration date. Shelf Life of the Xpert Urine Transport Reagent Kit is 24 months.

1. Requirement: ≥ 4.5 mL of urine specimen that is not from the first void of the day.
2. Invert the urine collection container three times to mix.
3. Open the Xpert Urine Transport Reagent Kit.

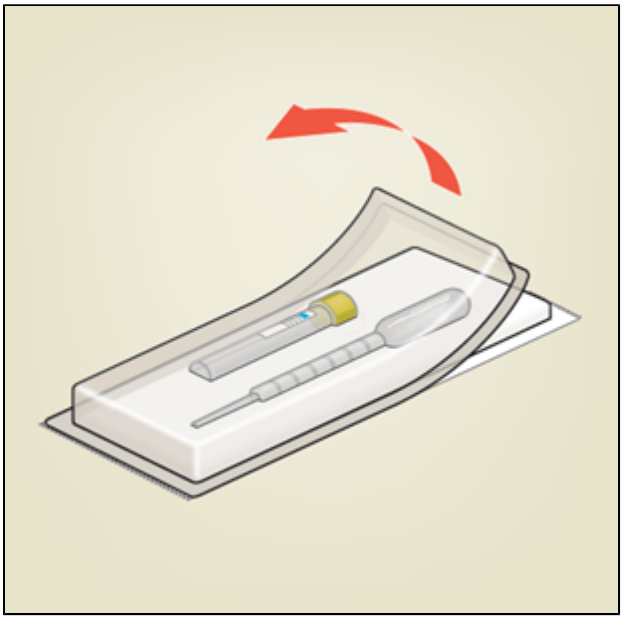

Figure 1: Open one Xpert Urine Transport Tube Reagent Kit.

4. Remove the cap from the Xpert Urine Transport Reagent tube.
5. Remove the cap from the urine collection container.
6. Use the transfer pipette to add 4.5 mL of urine to the "fill to" line (9 mL) on the tube.

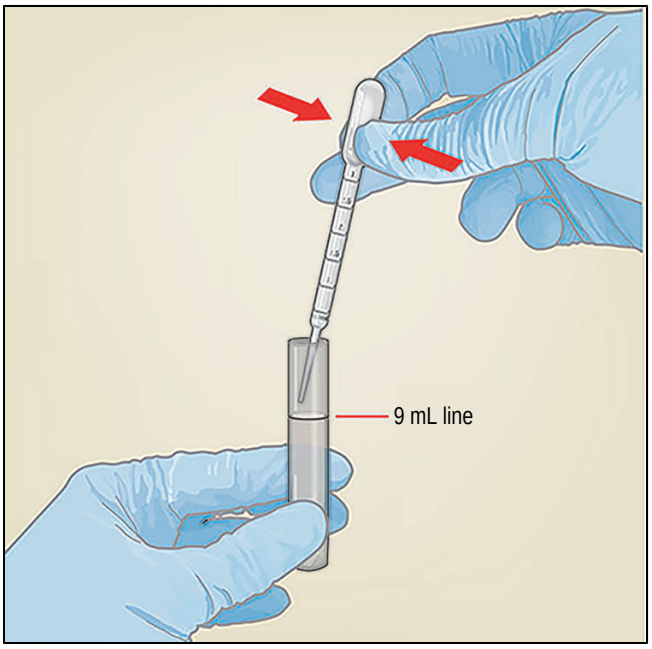

Figure 2: Add urine specimen to Xpert Urine Transport Reagent tube.

7. Replace the tube cap and tighten.

8. Invert the tube three times to mix.
9. Store Xpert Urine Transport Reagent tube with urine specimen at 2°C –28 °C up to 7 days or transport to the laboratory for testing on the Xpert Bladder Cancer Monitor or the Xpert Bladder Cancer Detection tests.

11 References

1. Centers for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories. 1993. Richmond JY and McKinney RW (eds). HHS Publication number (CDC) 93-8395.
2. Clinical and Laboratory Standards Institute. Protection of laboratory work Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (refer to latest edition).

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
REF	Catalog Number
LOT	Batch code
IVD	In vitro Diagnostic medical device
CE	CE-marking – European Conformity
EC REP	Authorized Representative in the European Community
	Legal manufacturer
2	Do not reuse
	Consult instructions for use

Symbol	Meaning
	Contains sufficient for *n* tests
	Temperature limitation
	Date of manufacture
	Caution
	Expiration date
	Biological Risk
	Warning

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Cepheid Europe SAS
Vira Solelh
81470 Maurens-Scopont
France

Importer Details for EU/Switzerland

Cepheid Netherlands BV
1e Tochtweg 11
2913LN
Nieuwerkerk aan den IJssel
Netherlands

Cepheid Switzerland GmbH
Zurcherstrasse 66
Postfach 124, Thalwil
CH-8800
Switzerland

14 Revision History

Description of Changes: 302-6829 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" changed to "test", instances of “sample(s)” changed to “specimen(s)”, instances of “package insert” changed to “Instructions for Use”, structure/order of sections updated.
Legal Page	Added Trademark, Patents and Copyright Statement page.
3	Added Proprietary Name, Intended Purpose, Intended User/Environment sections per IVDR requirements.
5	Added Principle of Procedure.
8	Added Warning Symbol. Added precautions to align with Cepheid similar collection kits. Added details to Chemical Hazards section from the Safety Data Sheet (available online.
9	Updated the specimen stability content.
10	Added pictures/images to illustrate the procedural steps.
13	Added symbols and the importer details for EU and Switzerland.
14	Added Revision History table.