

Xpert[®] Nasopharyngeal Sample Collection Kit (For Viruses)

REF SWAB/B-100

Instructions for Use

IVD CE

Trademark, Patents and Copyright Statements

Cepheid[®], the Cepheid logo, GeneXpert[®], and Xpert[®] are trademarks of Cepheid, registered in the U.S. and other countries. All other trademarks are the property of their respective owners.

THE PURCHASE OF THIS PRODUCT CONVEYS TO THE BUYER THE NON-TRANSFERABLE RIGHT TO USE IT IN ACCORDANCE WITH THESE INSTRUCTIONS FOR USE. NO OTHER RIGHTS ARE CONVEYED EXPRESSLY, BY IMPLICATION OR BY ESTOPPEL. FURTHERMORE, NO RIGHTS FOR RESALE ARE CONFERRED WITH THE PURCHASE OF THIS PRODUCT.

© 2014–2022 Cepheid.

See Section 15, Revision History for a description of changes.

Xpert® Nasopharyngeal Sample Collection Kit

In Vitro Diagnostic Medical Device



1 Proprietary Name

The Xpert® Nasopharyngeal Sample Collection Kit

2 Common or Usual Name

Xpert Nasopharyngeal Sample Collection Kit

3 Intended Purpose

3 Intended Use

The Xpert® Nasopharyngeal Sample Collection Kit is intended for the collection and transport of nasopharyngeal swab specimens containing viruses from patients with signs and symptoms of respiratory infection from the collection site to testing laboratory prior to analysis with Xpert and Xpress tests.

3.1 Intended User/Environment

The Xpert® Nasopharyngeal Sample Collection Kit (For Viruses) is intended to be used by trained users.

4 Summary and Explanation

Refer to the Instructions for Use for Xpert and Xpress tests (as appropriate).

5 Principles of the Procedure

The Copan Universal Transport Medium (UTM-RT) consists of modified Hank's balanced salt solution supplemented with bovine serum albumin, cysteine, gelatin, sucrose, and glutamic acid. The pH is buffered with HEPES buffer. Phenol red is used to indicate pH. Vancomycin, amphotericin B, and colistin are incorporated in the medium to inhibit growth of competing bacteria and yeast. The medium is isotonic and non-toxic to mammalian host cells. The presence of sucrose acts as a cryoprotectant, which aids in the preservation of respiratory viruses if specimens are frozen (-70°C) for prolonged storage.

6 Reagents

6.1 Materials Provided

Xpert Nasopharyngeal Sample Collection Kit (quantity: 100)

Each kit includes a sealed package containing:

- 1 individually wrapped sterile nylon flocked nasopharyngeal swab
- 1 Copan Universal Transport Medium (UTM-RT) tube containing:
 - Hank's Balanced Salts
 - Bovine Serum Albumin
 - L-Cysteine
 - Gelatin
 - Sucrose
 - L-Glutamic Acid
 - HEPES Buffer
 - Vancomycin
 - Amphotericin B
 - Colistin
 - Phenol Red
 - pH 7.3 ± 0.2 @ 25 °C

6.2 Materials Needed but Not Provided

- Disposable gloves
- Adhesive labels or permanent markers for recording specimen information

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

Note The bovine serum albumin (BSA) within this product was produced and manufactured exclusively from bovine plasma sourced in New Zealand. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and post-mortem testing. During processing, there was no mixing of the material with other animal materials.

7 Warnings and Precautions

- For prescription use only.
- Do not re-sterilize unused swabs.
- Do not re-pack.
- Not suitable to collect and transport microorganisms other than respiratory viruses.
- Not suitable for any other application than the intended use.
- Do not use if the swab is visibly damaged (i.e., if the swab tip is broken).
- Do not ingest the medium.
- Do not use the Copan Universal Transport Medium (UTM-RT) for premoistening or prewetting the applicator swab prior to collecting the sample or for rinsing or irrigating the sampling sites.
- Do not bend the swab prior to specimen collection.
- Specimen collection and handling procedures require specific training and guidance.
- Observe approved biohazard precautions and aseptic techniques.
- To be used only by adequately trained and qualified personnel.
- All biological specimens should be considered potentially infectious and handled in a manner that prevents infection of laboratory personnel.
- Sterilize all biohazardous waste, including specimens, containers, and media after their use.
- Directions should be read and followed carefully.

8 Chemical Hazards

According to Regulations (EC) No. 1272/2008 CLP and (OSHA) CFR 29 1910 1220, this material is not considered hazardous.

9 Kit Storage Requirements

The product should be stored in its original container at 2 °–25 °C. Do not overheat. Do not incubate or freeze prior to use. Improper storage will result in a loss of efficacy. Do not use after the expiration date, which is clearly printed on the outer box label.

9.1 Product Deterioration

The Xpert Nasopharyngeal Sample Collection Kit should not be used if (1) there is evidence of damage or contamination to the product, (2) there is evidence of leakage, (3) the color of the medium has changed from light orange-red, (4) the expiration date has passed on any of the components, (5) the swab pouch is open, or (6) there are other signs of deterioration on any of the components.

10 Limitations

- Specimens should be handled aseptically.
- The Xpert Nasopharyngeal Sample Collection Kit is intended for use as a collection and transport medium for respiratory viruses only.
- The Xpert Nasopharyngeal Sample Collection Kit is intended to be used with the medium tube and swab provided in the kit. The use of tubes of medium or swabs from any other source could affect the performance of the product.

11 Specimen Collection and Handling

Nasopharyngeal swab specimens can be collected following the user institution's standard procedures and placed into the Copan Universal Transport Medium (UTM-RT) (3 mL tube with transport media). Samples should be transported at 2-8 °C.

12 Sample Collection Procedure

Proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms. Highest viral titers are present during the acute illness.

Note The nylon flocked swab should not be bent prior to specimen collection.

1. Collect the specimen with the swab. Take care not to touch the tip of the swab and not to lay it down.
2. Aseptically remove the cap from the tube.
3. Insert the swab into the tube with the transport medium.
4. Break the swab shaft at the pre-scored line by bending it against the tube wall. If needed, gently rotate the Swab shaft to complete the breakage.
5. Replace the cap onto the tube and close tightly.
6. Label with appropriate patient information.
7. Send to the laboratory or testing area for immediate analysis.

13 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
 Email: support@cepheideurope.com

Contact information for all Cepheid Technical Support offices is available on our website: www.cepheid.com/en/support/contact-us

14 Table of Symbols

Symbol	Meaning
	Catalog number
	CE marking – European Conformity
	<i>In vitro</i> diagnostic medical device
	Contains sufficient for <i>n</i> tests
	Sterilized using ethylene oxide
	Authorized Representative in the European Community
	Do not reuse
	Manufacturer
	Temperature limitation
	Batch code
	Caution
	Consult instructions for use
	Expiration date
	Biological risks
	For prescription use only.
	Handle with care



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

15 Revision History

Description of Changes: 302-6819 Rev B.

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

Section	Description of Change
Legal Page	Added Trademark, Patents and Copyright Statement page.