

cobas[®] PCR Urine Sample Kit

FOR IN VITRO DIAGNOSTIC USE.

cobas[®] PCR Urine Sample Kit

100 Packets

P/N: 05170486190

INTENDED USE

The cobas[®] PCR Urine Sample Kit is used to collect and transport urine specimens. The cobas[®] PCR Media serves as a nucleic acid stabilizing transport and storage medium for urine specimens.

Refer to the assay-specific Instructions for Use for further information.

CONTENTS

Each cobas[®] PCR Urine Sample Kit contains 100 cobas[®] PCR Urine Sample Packets.

Each cobas[®] PCR Urine Sample Packet contains one vial of cobas[®] PCR Media and one disposable transfer pipette.

KIT AND PACKET STORAGE REQUIREMENTS

Store at 15°C to 30°C.

WARNINGS AND PRECAUTIONS

cobas[®] PCR Media contains guanidine hydrochloride. Do not allow direct contact between guanidine hydrochloride and sodium hypochlorite (bleach) or other highly reactive reagents such as acids and bases. These mixtures can release a noxious gas.

- If cobas[®] PCR Media is spilled, **FIRST** clean with a suitable laboratory detergent and water, and then with 0.5% sodium hypochlorite.
- Avoid contact of the cobas[®] PCR Media with the skin, eyes or mucous membranes. If contact does occur, immediately wash with large amounts of water.

For in vitro diagnostic use only.

Carefully follow the instructions, as shown below to ensure correct sample collection.

Wear protective disposable gloves, coats, and eye protection when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and kit reagents.

If the collected urine contains excess blood (specimen has a dark red or brown color) it should be discarded and not used for testing.

While unlikely to be present in urine specimens, vaginal lubricants, speculum jellies, creams and gels containing carbomer(s) may interfere with the test and should not be used during or prior to sample collection.

Urogenital specimens from patients who have used carbomer-containing products such as Replens[™] Long-Lasting Vaginal Moisturizer, RepHresh[™] Odor Eliminating Vaginal Gel and RepHresh[™] Clean Balance or used Metronidazole Vaginal Gel may generate invalid or false negative results. Refer to the appropriate test's Instructions For Use for further details.

Specimens should be handled as if infectious using safe laboratory procedures such as those outlined in *Biosafety in Microbiological and Biomedical Laboratories*¹ and in the CLSI Document M29-A3².

Dispose of unused reagents, waste and specimens in accordance with all applicable regulations.

Each cobas[®] PCR Urine Sample Packet is for single-use. Do not reuse any component of a cobas[®] PCR Urine Sample Packet.

Do not use a damaged or leaking cobas[®] PCR Media tube or disposable transfer pipette.

Do not use a kit after its expiration date.

Safety Data Sheets (SDS) are available on request from your local Roche office.

Inform your local competent authority about any serious incidents which may occur when using this device.

MATERIALS PROVIDED

cobas[®] PCR Urine Sample Kit x 100 packets
(P/N: 05170486190)

cobas[®] PCR Urine Sample Packet

Disposable pipette x 1 pc

cobas[®] PCR Media 1 x 4.3 mL

≤ 40% (w/w) Guanidine hydrochloride
Tris-HCl buffer



WARNING

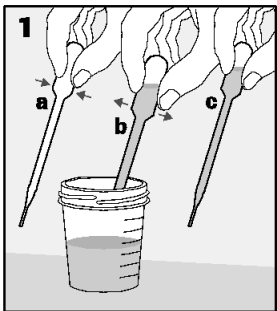
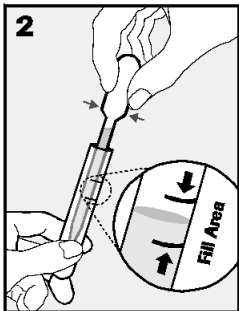
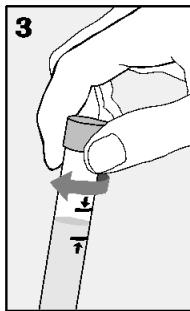
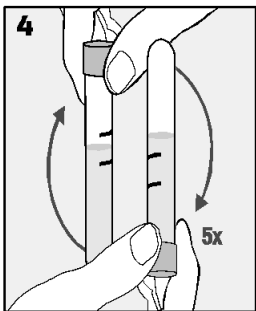
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
P264	Wash skin thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/ eye protection/ face protection.
P301 + P312 + P330	IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P337 + P313	If eye irritation persists: Get medical advice/ attention.
P501	Dispose of contents/ container to an approved waste disposal plant.
50-01-1	Guanidinium chloride

NOTE: Product safety labeling primarily follows EU GHS guidance.

SPECIMEN COLLECTION

COLLECT: Prior to sampling, the patient should not have urinated for at least one hour. Given that collection of larger volumes of urine may reduce test sensitivity, please direct patient to provide first-catch urine (approximately 10 to 50 mL of the initial urine stream) into a urine collection cup (not provided).

NOTE: For best results, female patients should not cleanse the labial area prior to collection.

 <p>1. PIPETTE: Immediately transfer the urine into the cobas[®] PCR Media tube using the provided disposable pipette. NOTE: If the urine specimen cannot be transferred immediately, it can be stored at 2°C to 30°C for up to 24 hours.</p>	 <p>2. TRANSFER: The correct volume of urine has been added when the fluid level is between the two black lines on the tube label.</p>	 <p>3. CAP: Tightly re-cap the cobas[®] PCR Media tube.</p>	 <p>4. MIX: Invert the tube 5 times to mix. The specimen is now ready for transport.</p>
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SPECIMEN TRANSPORT AND STORAGE

Urine specimens must be transferred into the **cobas**[®] PCR Media tube (stabilized) immediately. If specimens cannot be transferred immediately, they can be stored at 2°C to 30°C for up to 24 hours.

Transport and store the **cobas**[®] PCR Media tube containing the stabilized urine specimen at 2°C to 30°C.

Consult the test-specific Instructions for Use for collected specimen stability claims.

Transportation of collected specimens must comply with all applicable regulations for the transport of etiologic agents³.

REFERENCES

1. Richmond, J.Y. and McKinney, R.W. eds. 1999. *Biosafety in Microbiological and Biomedical Laboratories*. HHS Publication Number (CDC) 93-8395.
2. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from occupationally acquired infections. Approved Guideline-Fourth Edition. CLSI Document M29-A4:Wayne, PA;CLSI, 2014.
3. International Air Transport Association. Dangerous Goods Regulations, 61st Edition. 2020.

Document Revision Information	
Doc Rev. 2.0 (Mfg-CN) 05/2024	Updated hazard information. Updated Trademarks and patents section, including the link. Added IVD symbol. Removed Rx Only from front page. Updated the harmonized symbol page. Please contact your local Roche Representative if you have any questions.

Technical support

For technical support (assistance) please reach out to your local affiliate:
https://www.roche.com/about/business/roche_worldwide.htm

Manufacturer and importer

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Roche Molecular Systems, Inc.
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Made in China



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Trademarks and Patents

See <https://diagnostics.roche.com/us/en/about-us/patents>

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The following symbols are now used in labeling for Roche PCR diagnostic products.

Age/DOB Age or Date of Birth


 Ancillary Software

 Device not for near-patient testing

 Device not for self-testing

QS IU/PCR QS IU per PCR reaction, use the QS International Units (IU) per PCR reaction in calculation of the results.

Assigned Range [copies/mL] Assigned Range (copies/mL)

 Distributor
(Note: The applicable country/region may be designated beneath the symbol)

SN Serial number

Assigned Range [IU/mL] Assigned Range (IU/mL)

 Do not re-use


Site Site

EC REP Authorized representative in the European Community

 Female

Procedure Standard Standard Procedure

BARCODE Barcode Data Sheet


 For IVD performance evaluation only

STERILE EO Sterilized using ethylene oxide

LOT Batch code

GTIN Global Trade Item Number

 Store in dark


 Biological risks

 Importer

 Temperature limit

REF Catalogue number

IVD In vitro diagnostic medical device

 Test Definition File

CE CE marking of conformity; this device is in conformity with the applicable requirements for CE marking of an in vitro diagnostic medical device

LLR Lower Limit of Assigned Range

 This way up


 Male

Procedure UltraSensitive Ultrasensitive Procedure

Collect Date Collect date


 Manufacturer

UDI Unique Device Identifier

 Consult instructions for use

CONTROL - Negative control


ULR Upper Limit of Assigned Range

 Contains sufficient for <n> tests

 Non-sterile


Urine Fill Line Urine Fill Line


CONTENT Content of kit


 Patient Name

Rx only For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.


CONTROL Control

 Patient number


 Use-by date

 Date of manufacture

 Peel here

 Device for near-patient testing

CONTROL + Positive control

 Device for self-testing

QS copies / PCR QS copies per PCR reaction, use the QS copies per PCR reaction in calculation of the results.