cobas® PCR Urine Sample Kit

Rx Only

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. Use this collection kit only with the following tests:

- **cobas®** CT/NG for use on **cobas®** 5800/6800/8800 Systems
- **cobas®** TV/MG for use on **cobas®** 5800/6800/8800 Systems
- **cobas®** BKV for use on **cobas®** 5800/6800/8800 Systems
- **cobas®** CT/NG v2.0 Test (for use on **cobas®** 4800 Systems)
- **cobas® liat** CT/NG nucleic acid test
- **cobas® liat** CT/NG/MG nucleic acid test

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.

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-A3[2].

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

Do not use a kit after its expiration date.

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

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

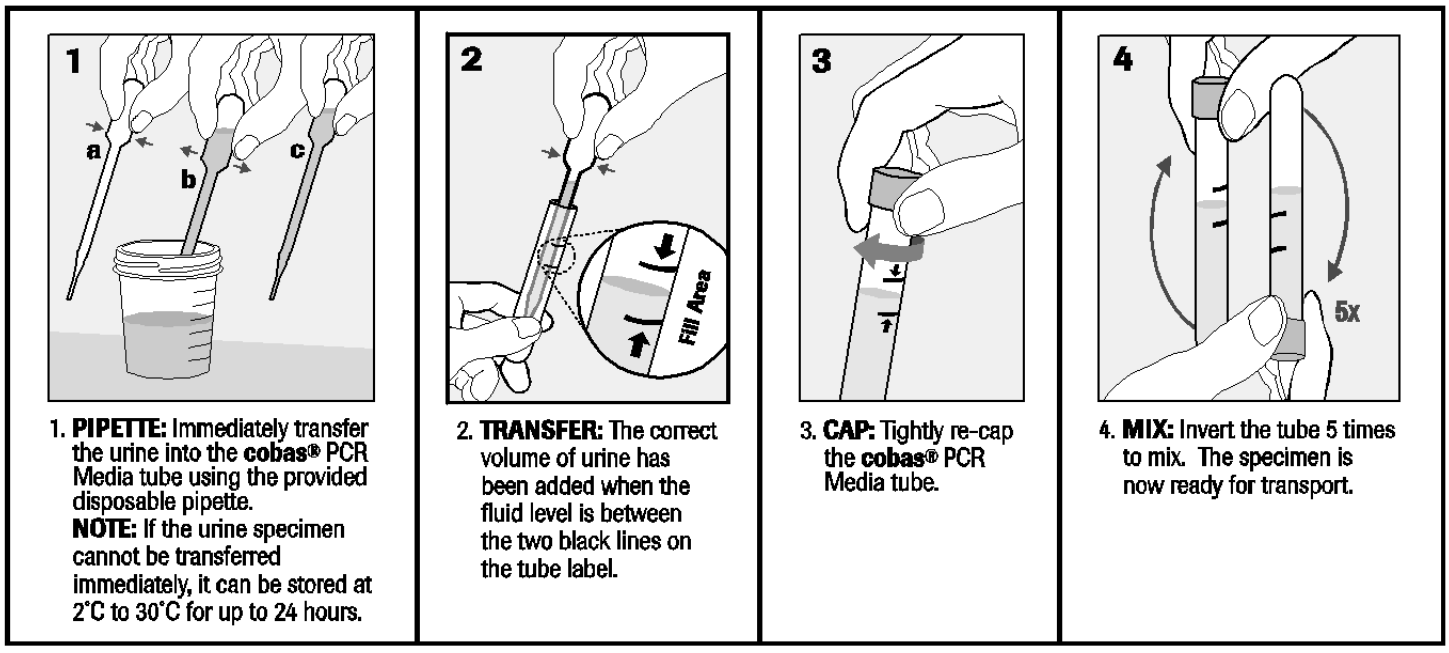
WARNING

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).



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.

2. **TRANSFER:** The correct volume of urine has been added when the fluid level is between the two black lines on the tube label.

3. **CAP:** Tightly re-cap the **cobas**® PCR Media tube.

4. **MIX:** Invert the tube 5 times to mix. The specimen is now ready for transport.

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 2ºC to 30ºC for up to 24 hours.

Transport and store the **cobas**® PCR Media tube containing the stabilized urine specimen at 2ºC to 30ºC.

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 agents[3].

REFERENCES

1. Center for Disease Control and Prevention. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health HHS Publication No. (CDC) 21-1112, revised December 2009.
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, 59th Edition. 2018.

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

Age/DOB — Age or Date of Birth

SW — Ancillary Software

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

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

EC REP — Authorized representative in the European Community

BARCODE — Barcode Data Sheet

LOT — Batch code

Biological risks

REF — Catalogue number

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

Collect Date — Collect date

Consult instructions for use

Σ — Contains sufficient for <*n*> tests

CONTENT — Content of kit

CONTROL — Control

Date of manufacture

Device for near-patient testing

Device for self-testing

Device not for near-patient testing

Device not for self-testing

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

Do not re-use

Female

For IVD performance evaluation only

GTIN — Global Trade Item Number

Importer

IVD — In vitro diagnostic medical device

LLR — Lower Limit of Assigned Range

Male

Manufacturer

CONTROL − — Negative control

NON STERILE — Non-sterile

Patient Name

Patient number

Peel here

CONTROL + — Positive control

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

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

SN — Serial number

Site — Site

Procedure Standard — Standard Procedure

STERILE EO — Sterilized using ethylene oxide

Store in dark

Temperature limit

TDF — Test Definition File

This way up

Procedure UltraSensitive — Ultrasensitive Procedure

UDI — Unique Device Identifier

ULR — Upper Limit of Assigned Range

Urine Fill Line — Urine Fill Line

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

Use-by date

Technical support

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

Manufacturer and distributor

Rx only

cobas® PCR Urine Sample Kit manufactured for:

Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876, USA
www.roche.com

Made in USA

Distributed by
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250-0457, USA
(For Technical Assistance call the
Roche Response Center
Toll-free: 1-800-526-1247)

Trademarks and patents

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

Document Revision Information	
Doc Rev. 12.0 05/2024	Updated hazard information. Updated the harmonized symbol page. Removed Rx only text from front page to above legal manufacturer. Please contact your local Roche Representative if you have any questions.
Doc Rev. 13.0 01/2025	Update IFU to including LIAT STI assay. Added Rx Only to front page. Please contact your local Roche Representative if you have any questions.