

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. Use this collection kit only with the cobas[®] 4800 CT/NG 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.

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.

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	IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P330	Rinse mouth.
P332 + P313	If skin irritation occurs: Get medical advice/ attention.
P337 + P313	If eye irritation persists: Get medical advice/ attention.
P362	Take off contaminated clothing and wash before reuse.
P501	Dispose of contents/ container to an approved waste disposal plant.

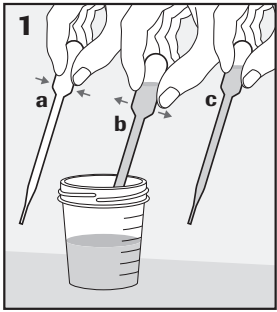
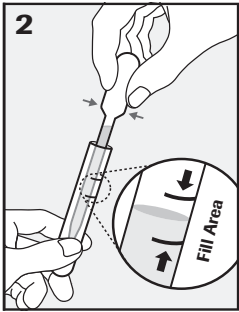
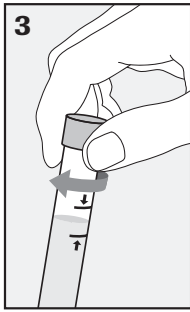
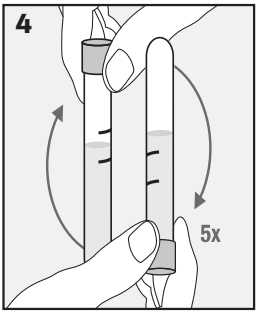
NOTE: Product safety labeling primarily follows EU GHS guidance.

The Document Revision Information section is located at the end of this document.

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.

Stabilized urine specimens are stable at 2°C to 30°C for up to 12 months.

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-Third Edition*. CLSI Document M29-A3 Wayne, PA:CLSI, 2005.
3. International Air Transport Association. *Dangerous Goods Regulations, 50th Edition*. 2009.

Document Revision Information

Doc Rev. 7.0 02/2015	Updated Hazard Labeling to meet new GHS Hazard requirements. Added GTIN symbol and description to the harmonized symbol page. Updated trademarks and patent section to reference online resource only. Please contact your local Roche Representative if you have any questions.
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Trademarks and Patents

See <http://www.roche-diagnostics.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		Do not reuse
	Authorised Representative In the European Community		Female
	Batch code		<i>In Vitro</i> Diagnostic Medical Device
	Catalogue Number		Male
	Collect date		Manufacturer
	Consult instructions for use		Non sterile
	Sufficient For		Patient ID
	Contents of kit		Patient Name
	Distributed by		Peel here
	Site		Urine fill line
	Sterilized using ethylene oxide		Use By
	Temperature Limitation		Global Trade Item Number
	This product fulfills the requirements of the European Directive 98/79 EC for <i>in vitro</i> diagnostic medical devices.		

US Customer Technical Support 1-800-526-1247