



cobas[®] PCR Media Uni Swab Sample Kit

For in vitro diagnostic use

cobas[®] PCR Media Uni Swab Sample Kit

P/N: 07958030190

Table of contents

Intended use	3
Reagents and materials.....	4
cobas® PCR Media Uni Swab Sample Kit.....	4
Precautions and handling requirements	5
Warnings and precautions	5
Reagent handling.....	5
Good laboratory practice.....	5
Specimen collection.....	6
Vaginal swab specimen collection – clinician collection	6
Specimen transport and storage	7
Vaginal swab specimen collection – self-collection in a clinical setting	8
Specimen transport and storage	9
Meatal swab specimen collection - clinician or self collected in a clinical setting.....	10
Specimen transport and storage	11
Oropharyngeal (throat) swab specimen collection.....	12
Specimen transport and storage	13
Anorectal (rectal) swab specimen collection	14
Specimen transport and storage	15
Additional information	16
Symbols.....	16
Manufacturer and distributors	17
Trademarks and patents.....	17
Copyright.....	17
References.....	18
Document revision.....	18

Intended use

The **cobas**® PCR Media Uni Swab Sample Kit is used to collect and transport human specimens. The **cobas**® PCR Media serves as a nucleic acid stabilizing transport and storage medium for human specimens.

Note: This kit has been validated for use with the following tests:

- **cobas**® 4800 CT/NG Test
- **cobas**® CT/NG for use on the **cobas**® 6800/8800 Systems
- **cobas**® TV/MG for use on the **cobas**® 6800/8800 Systems
- **cobas**® Cdiff Test for use on the **cobas**® 4800 System
- **cobas**® Cdiff Test for use on the **cobas**® Liat® System


Refer to the assay-specific Instructions for Use for particular specimen claims.

Reagents and materials

cobas® PCR Media Uni Swab Sample Kit

All unopened kits shall be stored as recommended in Table 1.

Table 1 cobas® PCR Media Uni Swab Sample Kit

cobas® PCR Media Uni Swab Sample Kit			
Store at 15-30°C 100 Packets (P/N 07958030190)			
Packet components	Reagent ingredients	Quantity per packet	Safety symbol and warning*
cobas® PCR Media	≤ 40% (w/w) Guanidine hydrochloride Tris-HCl buffer	1 x 4.3 mL	 <p>Warning</p> <p>H302: Harmful if swallowed.</p> <p>H315: Causes skin irritation.</p> <p>H319: Causes serious eye irritation.</p> <p>P264: Wash skin thoroughly after handling.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P280: Wear protective gloves/ eye protection/ face protection.</p> <p>P301 + P312 + P330: IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.</p> <p>P337 + P313: If eye irritation persists: Get medical advice/ attention.</p> <p>P501: Dispose of contents/ container to an approved waste disposal plant.</p>
Swab Envelope	1 woven swab (polyester bud)	1 swab	Not applicable

*Product safety labeling primarily follows EU GHS guidance

Precautions and handling requirements

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.

- For *in vitro* diagnostic use only.
- Carefully follow the instructions, as shown below.
- 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.
- If the collected specimen contains excess blood (specimen has a 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 Laboratories¹ and in the CLSI Document M29-A4.²
- Safety Data Sheets (SDS) are available on request from your local Roche representative.

Reagent handling

- If cobas® PCR Media is spilled, **FIRST** clean with a suitable laboratory detergent and water, and then with 0.5% sodium hypochlorite.
- Dispose of unused reagents, waste and specimens in accordance with all applicable regulations.
- Do not use a kit after its expiration date.
- Ensure that the cap is tightened when closing the cobas® PCR Media Tube.
- Do not pre-wet swab in cobas® PCR Media before collection.

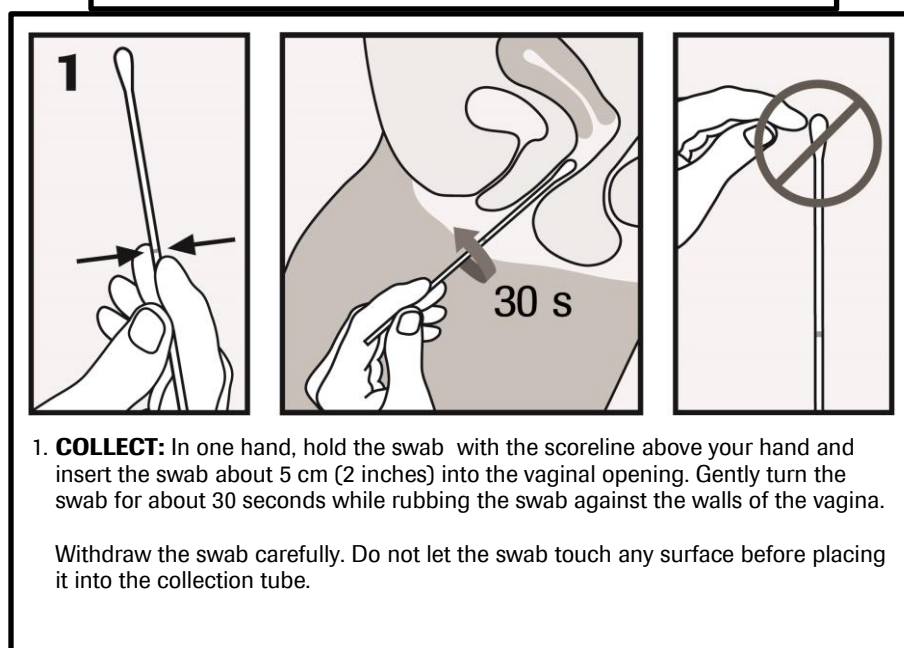
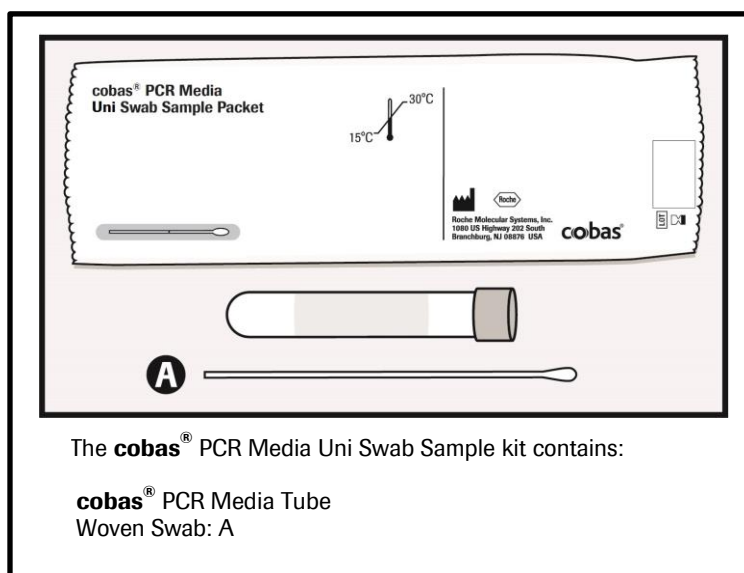
Good laboratory practice

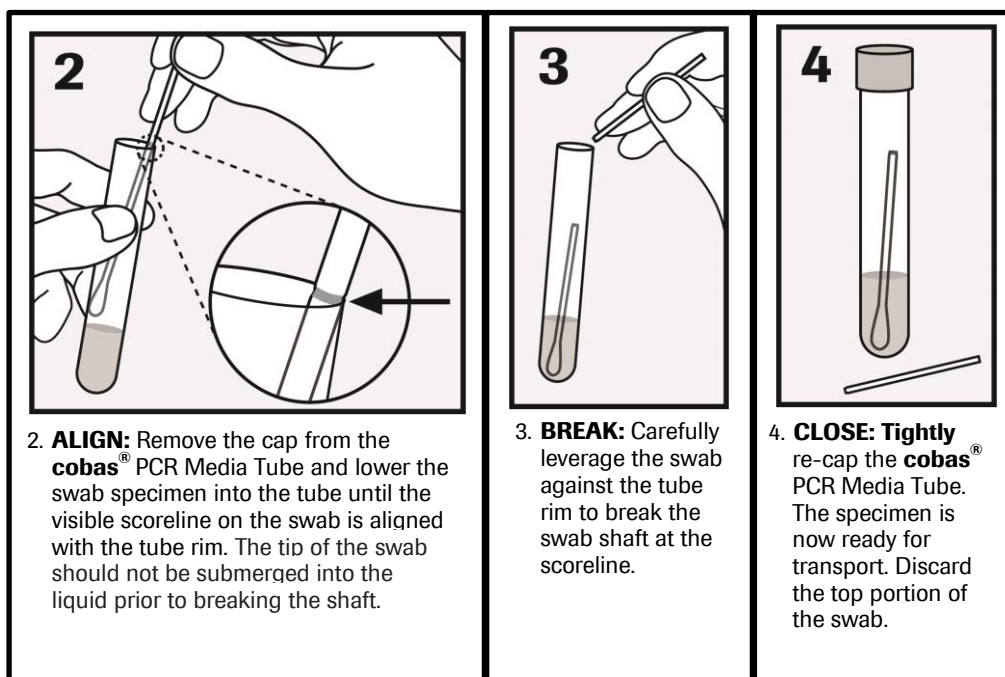
- Always follow Good Laboratory Practices/Good Clinical Practices (GLP/GCP).
- Wear protective disposable gloves, coats, and eye protection when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and kit reagents.

Specimen collection

Vaginal swab specimen collection – clinician collection

WARNING: DO NOT PRE-WET SWAB IN cobas® PCR MEDIA BEFORE COLLECTION!



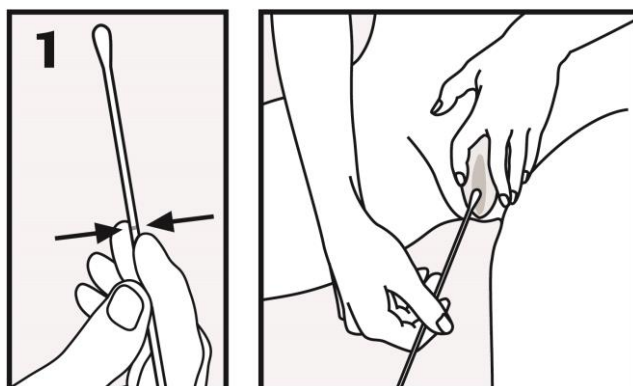
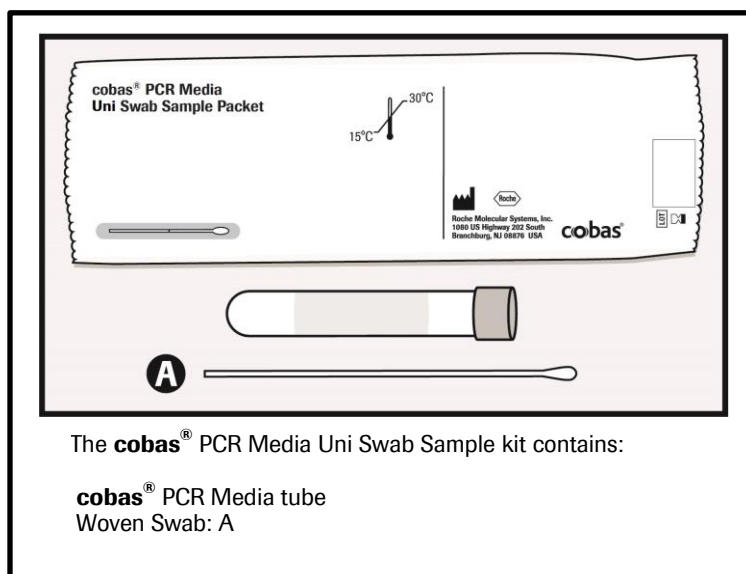


Specimen transport and storage

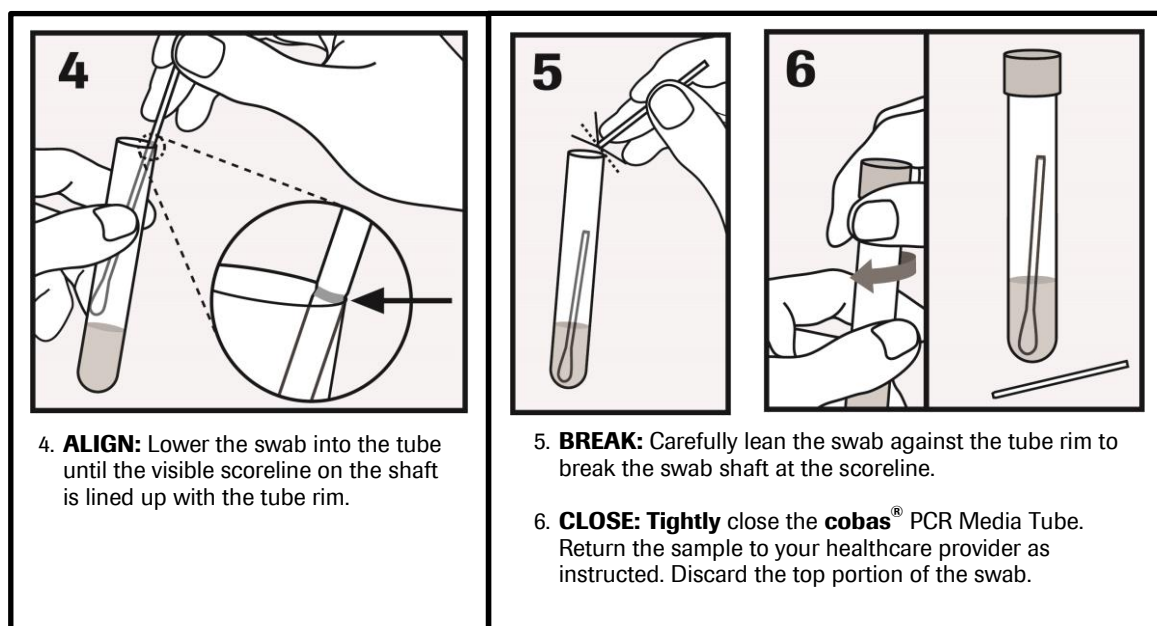
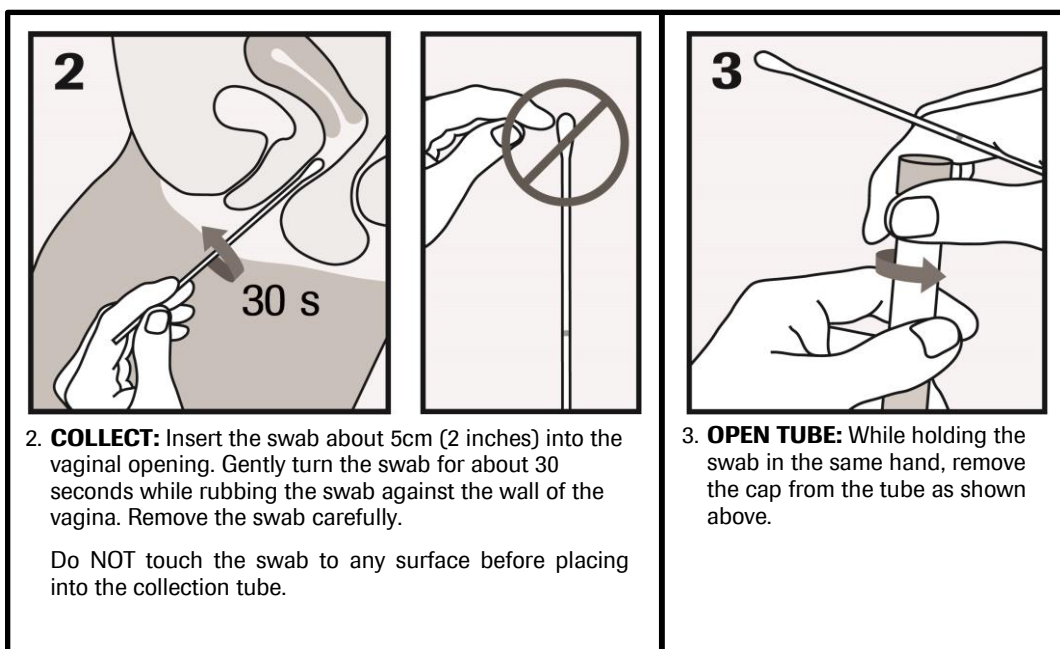
- Following specimen collection, transport and store the **cobas**® PCR Media Tube containing the collection swab at 2°C to 30°C.
- Consult the test-specific Instructions for Use for collected specimen stability claims.
- Transportation of collected specimens must comply with all applicable regulations for the transport of etiologic agents.³

Vaginal swab specimen collection – self-collection in a clinical setting

WARNING: DO NOT PRE-WET SWAB IN cobas® PCR MEDIA BEFORE COLLECTION!

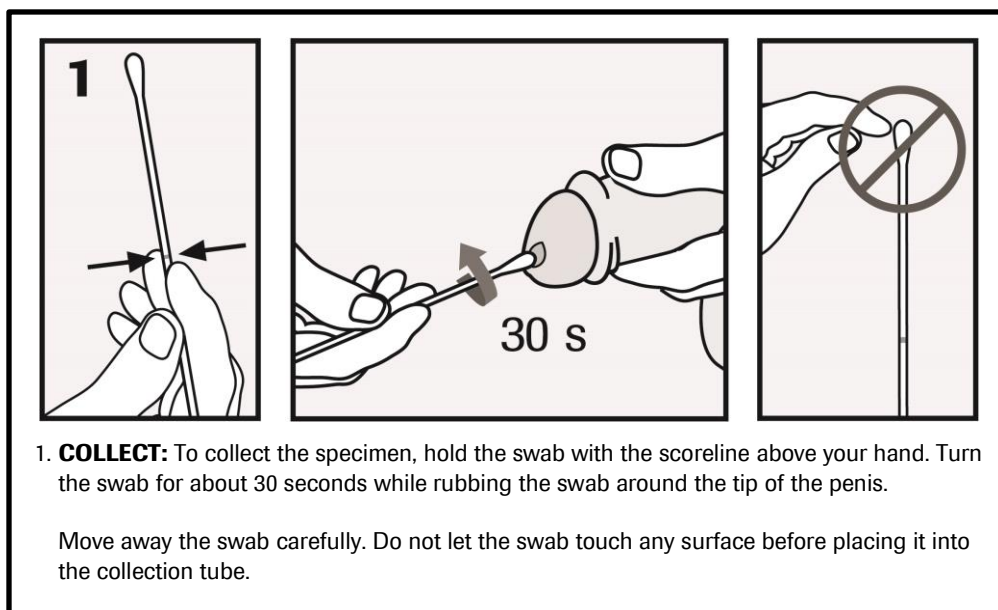
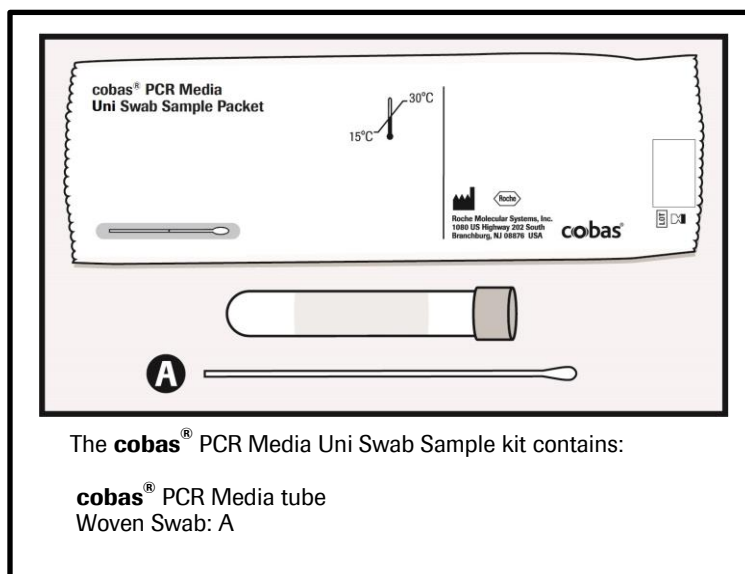


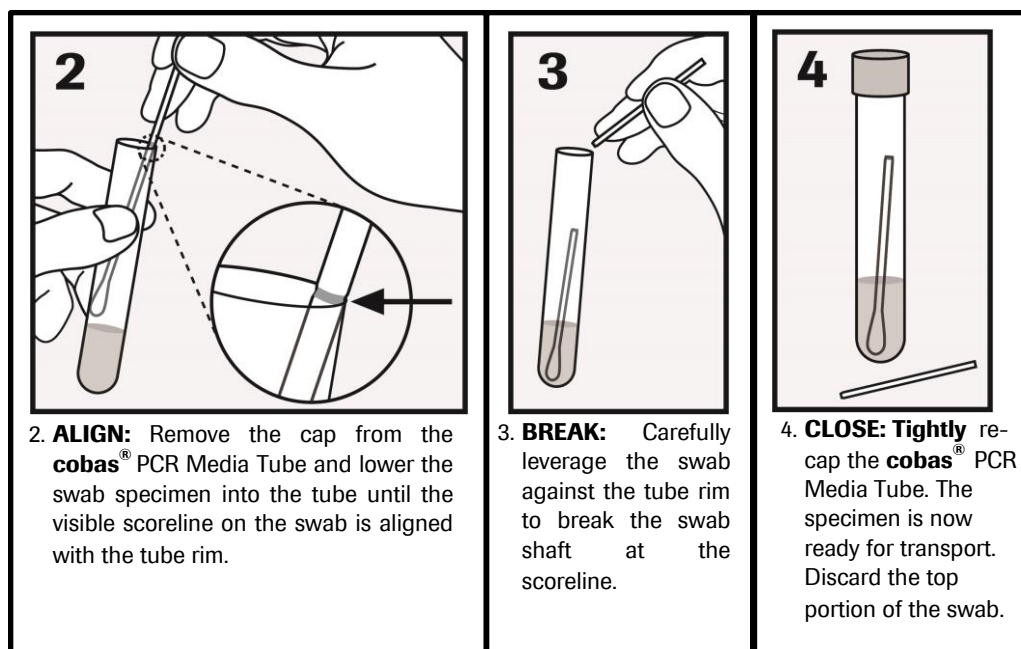
- 1. POSITION:** In one hand, hold the swab with the scoreline above your hand and with the other hand separate the folds of skin around the vaginal opening (labia).



Specimen transport and storage

- Following specimen collection, transport and store the cobas® PCR Media Tube containing the collection swab 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 agents.³

Meatal swab specimen collection - clinician or self collected in a clinical setting**WARNING: DO NOT PRE-WET SWAB IN cobas® PCR MEDIA BEFORE COLLECTION!**

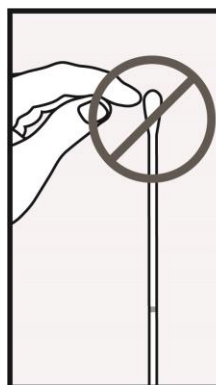
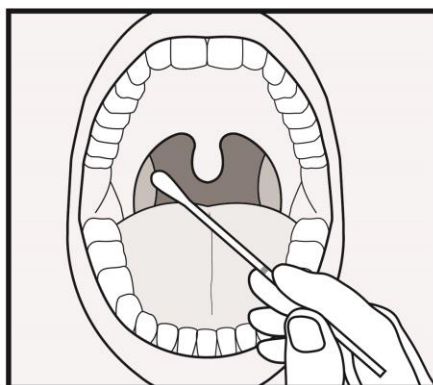
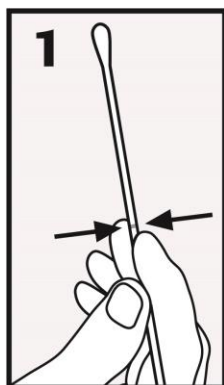
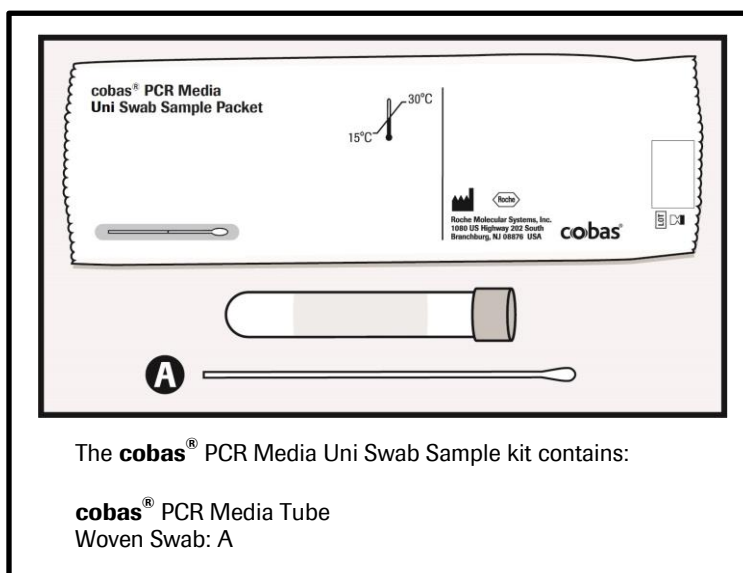


Specimen transport and storage

- Following specimen collection, transport and store the **cobas**® PCR Media Tube containing the collection swab 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 agents.³

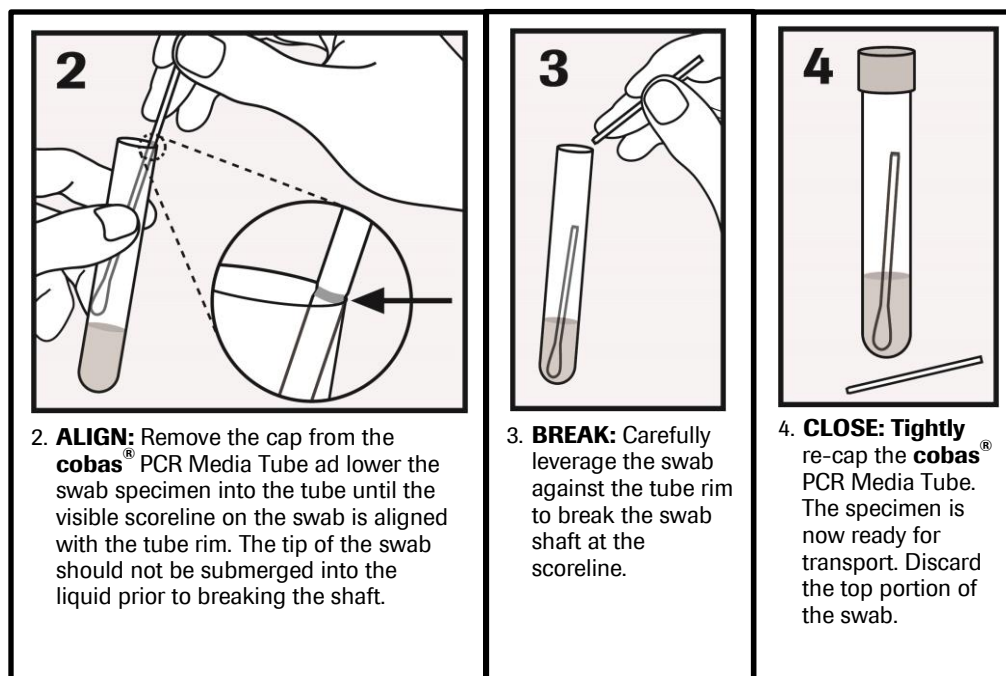
Oropharyngeal (throat) swab specimen collection

WARNING: DO NOT PRE-WET SWAB IN cobas® PCR MEDIA BEFORE COLLECTION!



1. **COLLECT:** To collect the specimen, hold the swab with the scoreline above your hand and insert the swab into the mouth and collect the specimen from the bilateral posterior pharynx, both tonsils and the uvula.

Withdraw the swab carefully. Do not let the swab touch any surface before placing it into the collection tube.

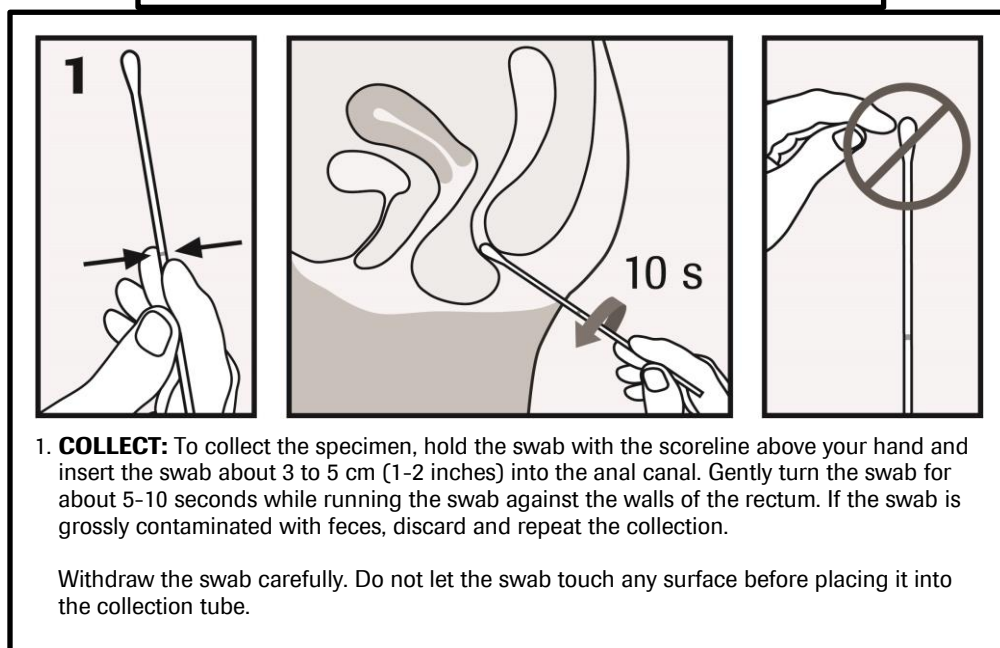
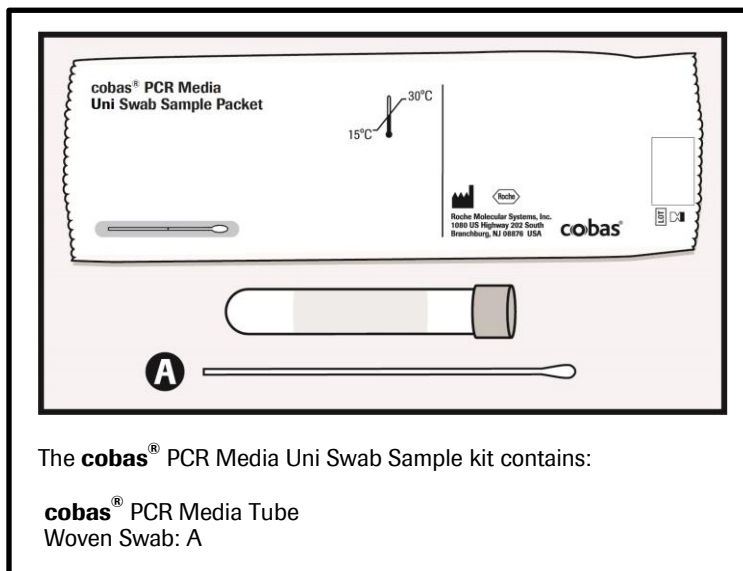


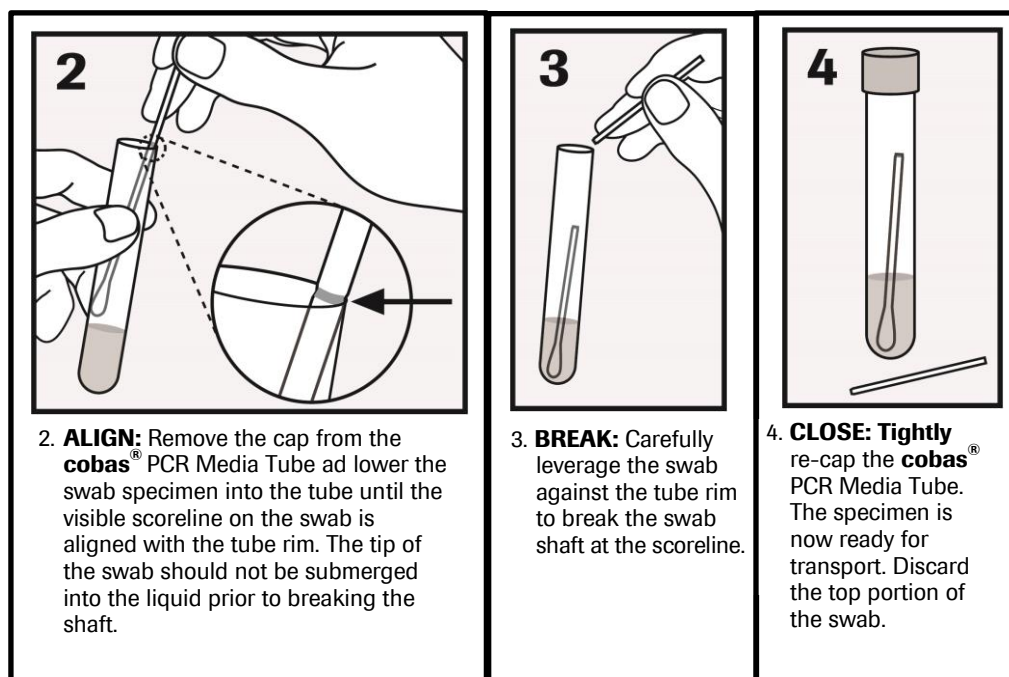
Specimen transport and storage

- Following specimen collection, transport and store the **cobas**® PCR Media Tube containing the collection swab 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 agents.³

Anorectal (rectal) swab specimen collection

WARNING: DO NOT PRE-WET SWAB IN cobas® PCR MEDIA BEFORE COLLECTION!






























Specimen transport and storage

- Following specimen collection, transport and store the **cobas**® PCR Media Tube containing the collection swab 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 agents.³

Additional information

Symbols

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

	Age or Date of Birth		Do not reuse
	Authorized 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
	Contains sufficient for <n> tests		Patient ID
	Contents of kit		Patient Name
	Distributed by		Peel here
	Site		Urine Fill Line
	Sterilized using ethylene oxide		Use-by date
	Temperature Limit		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

Manufacturer and distributors



Manufactured for:

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



Roche Diagnostics
201, boulevard Armand-Frappier
H7V 4A2 Laval, Québec, Canada
(For Technical Assistance call:
Pour toute assistance technique,
appeler le: 1-877-273-3433)

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Roche Diagnostics S.p.A
Viale G. B. Stucchi 110
20052 Monza, Milano, Italy

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany

Roche Diagnostics (Schweiz) AG
Industriestrasse 7
6343 Rotkreuz, Switzerland

Roche Diagnostics, SL
Avda. Generalitat, 171-173
E-08174 Sant Cugat del Vallès
Barcelona, Spain

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Estrada Nacional, 249-1
2720-413 Amadora, Portugal

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38240 Meylan, France

Roche Diagnostica Brasil Ltda
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05321-010 São Paulo, SP Brazil

Trademarks and patents

See <http://www.roche-diagnostics.us/patents>

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Germany



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, 52nd Edition. 2011.

Document revision

Document Revision Information	
Doc Rev. 1.0 10/2016	First Publishing.
Doc Rev. 2.0 04/2017	Added statement "Refer to the assay-specific Instructions for Use for particular specimen claims" and removed reference to cobas® CT/NG v2.0 Test in the Intended use section. Please contact your local Roche Representative if you have any questions.
Doc Rev. 3.0 10/2017	Added cobas® TV/MG to the list of tests in the Intended use section. Added Meatal swab specimen section. Please contact your local Roche Representative if you have any questions.