



cobas[®] PCR Media Uni Swab Sample Kit

For in vitro diagnostic use

cobas[®] PCR Media Uni Swab Sample Kit

P/N: 07958030190

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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 cobas® CT/NG, cobas® CT/NG v2.0 Test, and cobas® Cdiff Test.

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

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.

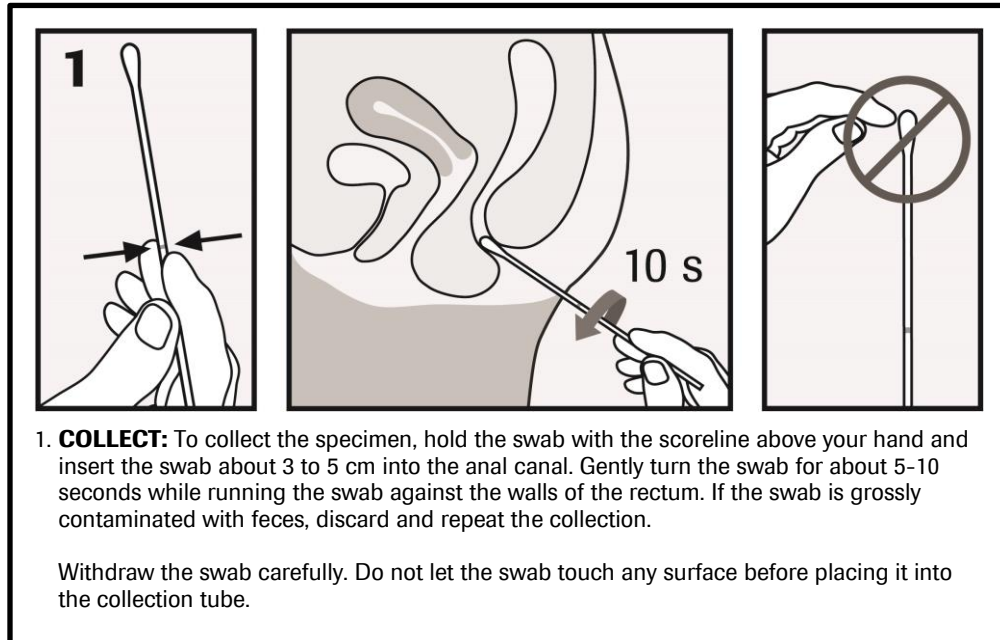
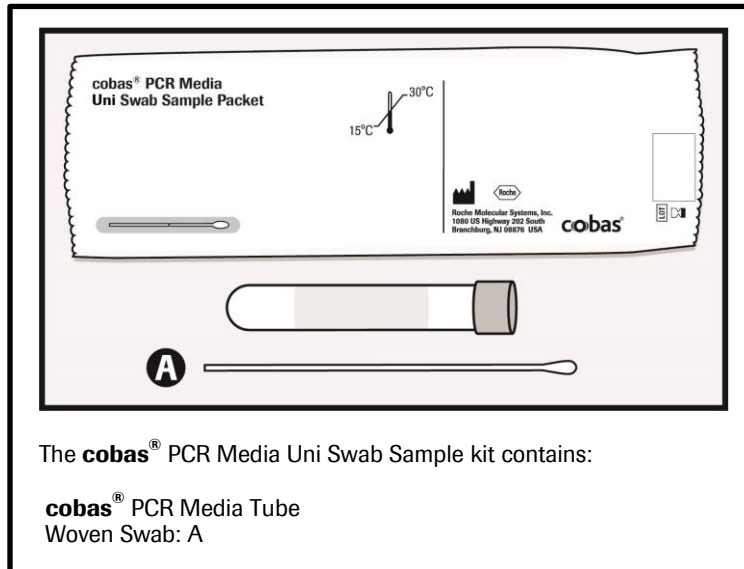
Good laboratory practice

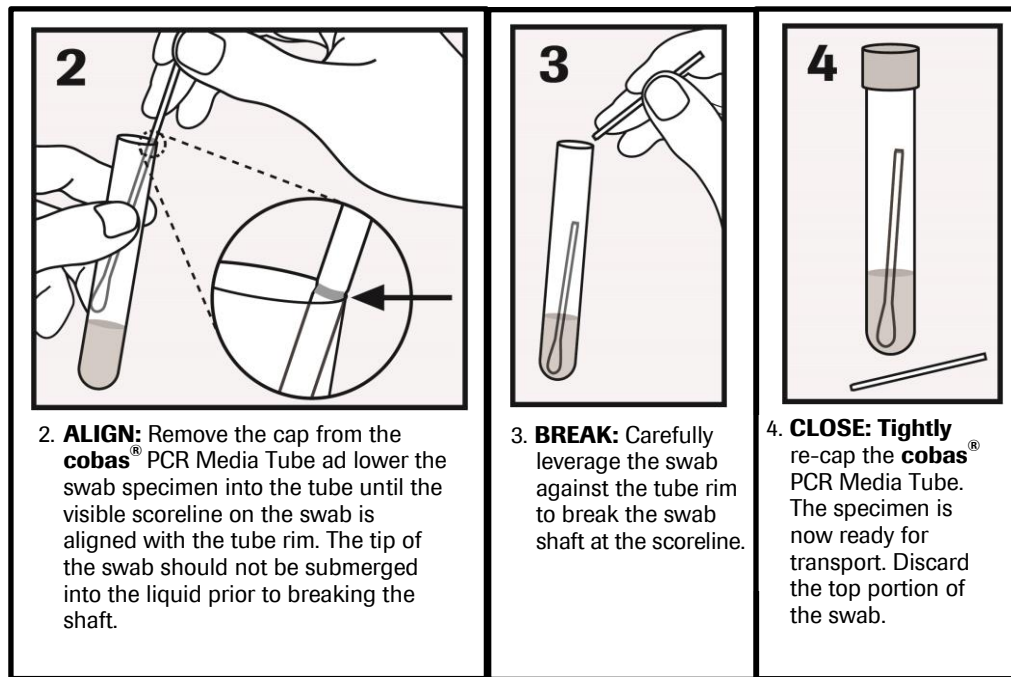
- Always follow Good Laboratory Practices/Good Clinical Practices (GLP/GCP).
- Wear protective disposable gloves, coats, and eye protection when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and kit reagents.

Specimen collection

Rectal swab specimen collection

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



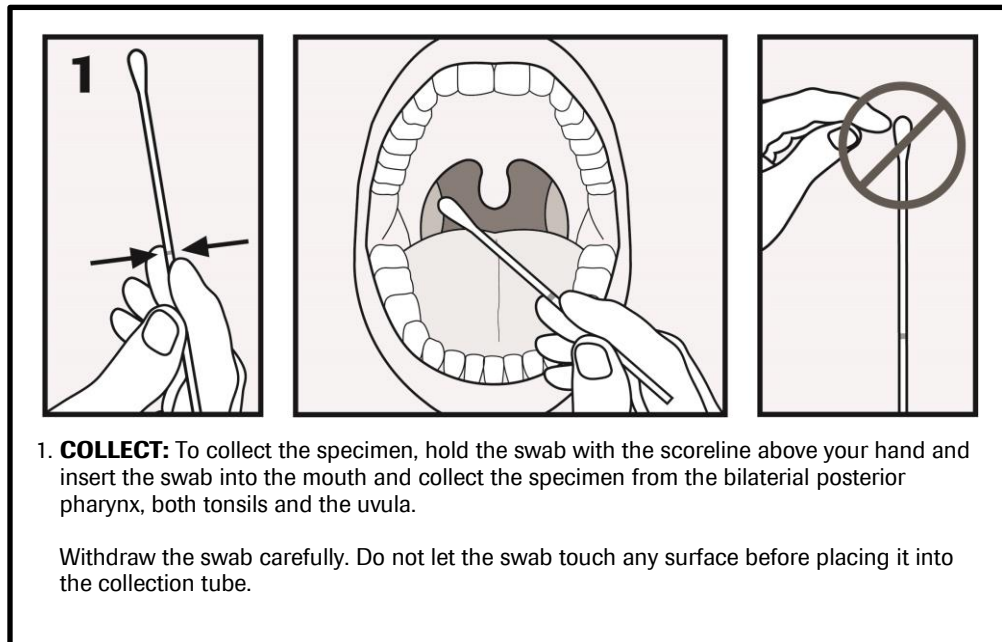
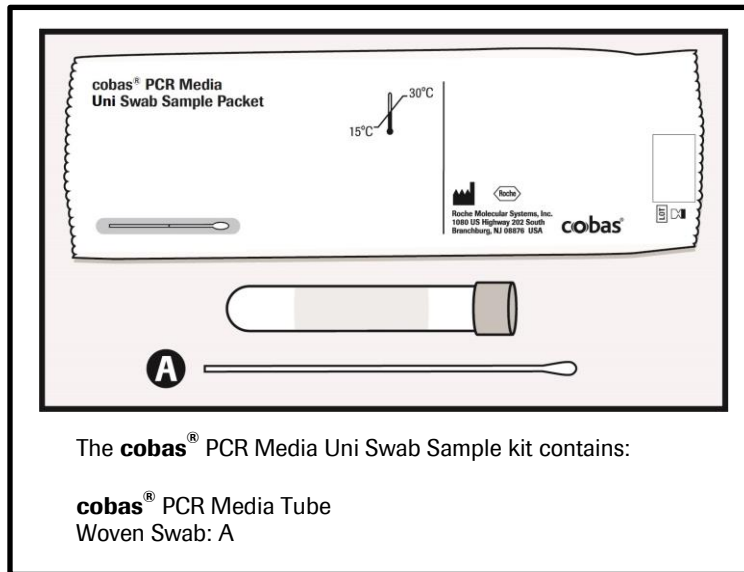


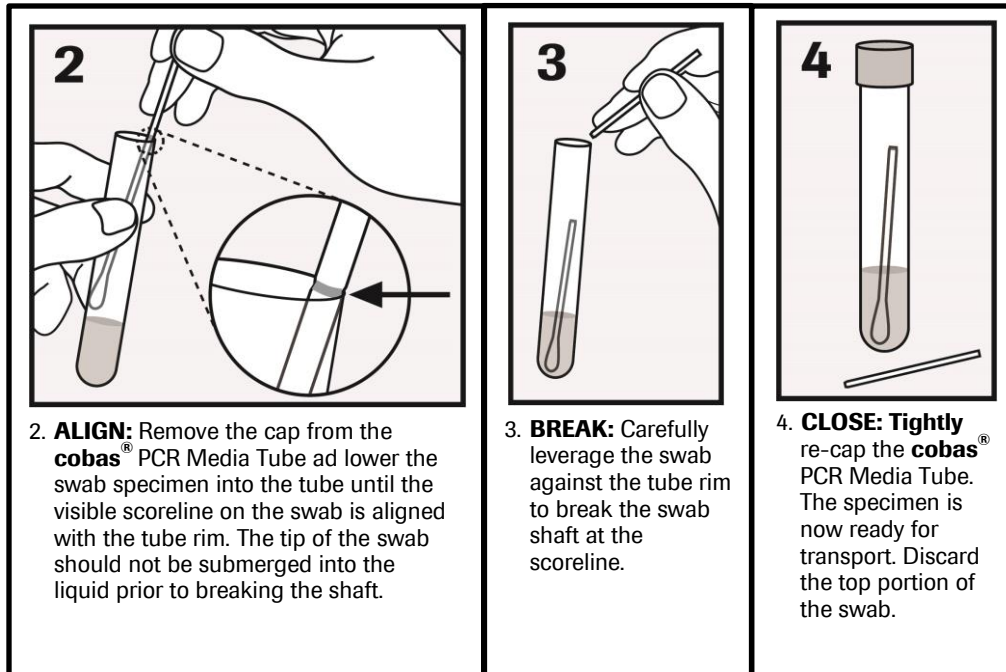
Specimen transport and storage

- 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

Throat swab specimen collection

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



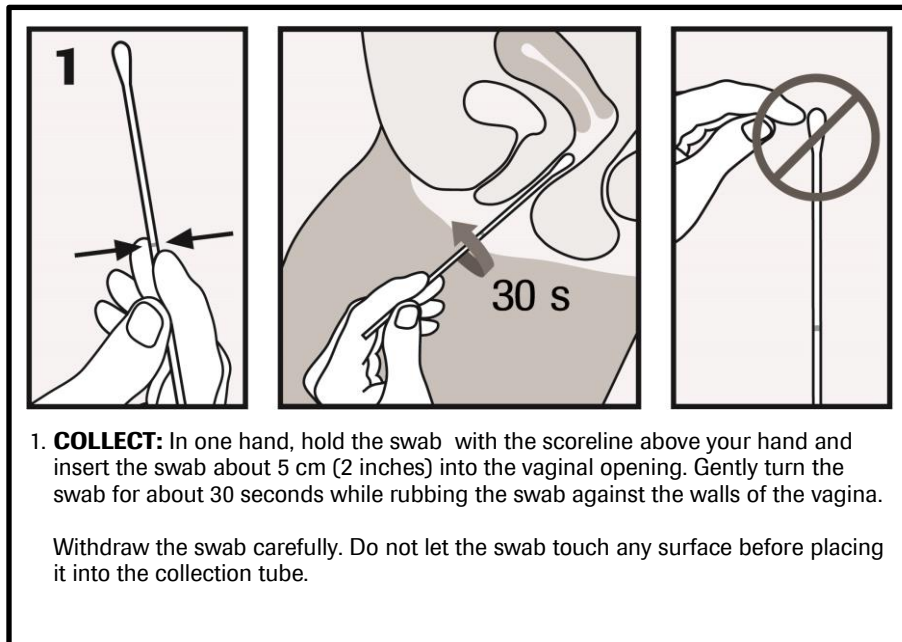
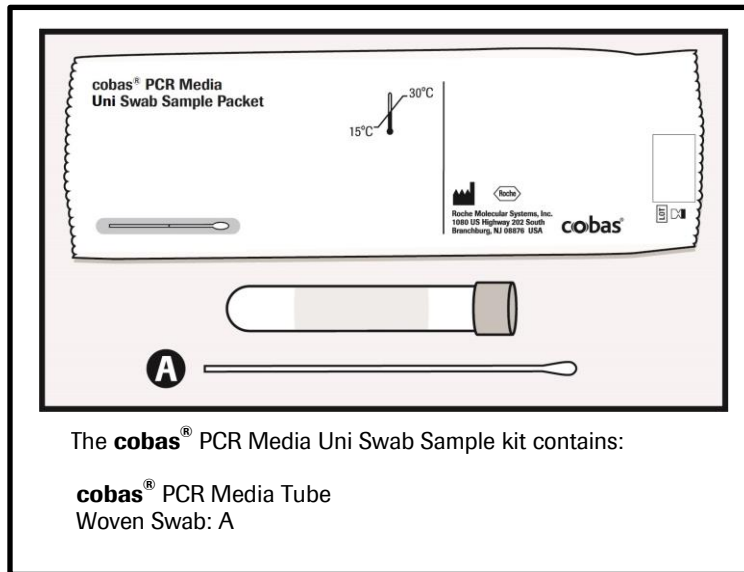


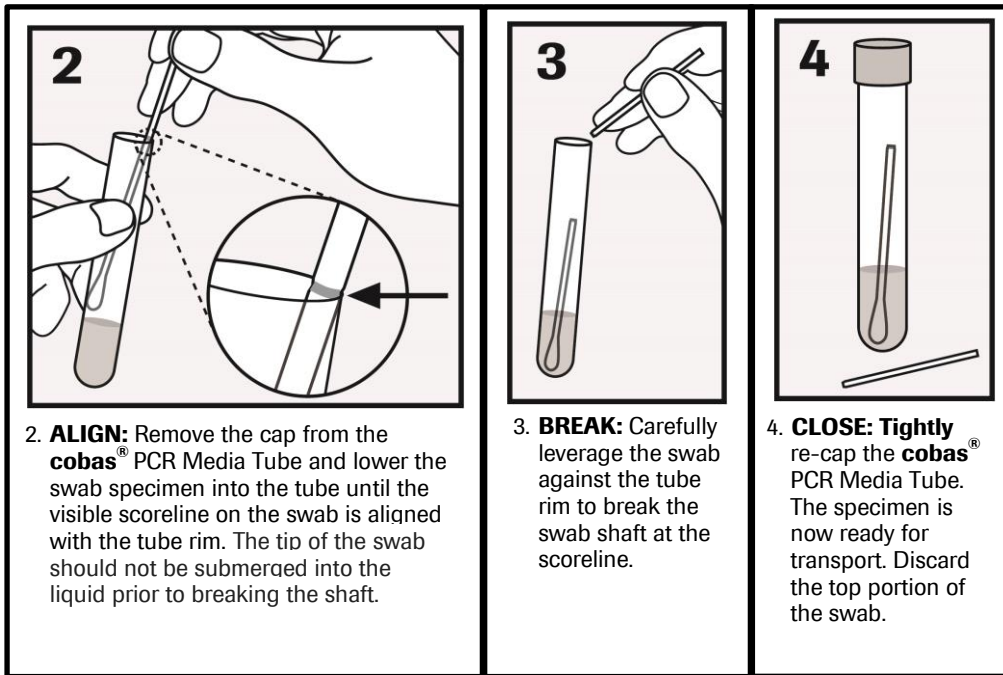
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Vaginal swab specimen collection – clinician collection

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



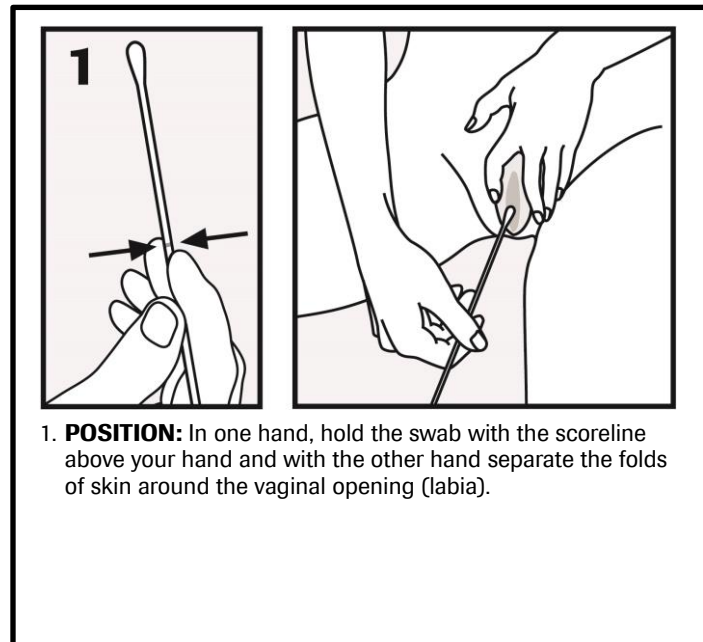
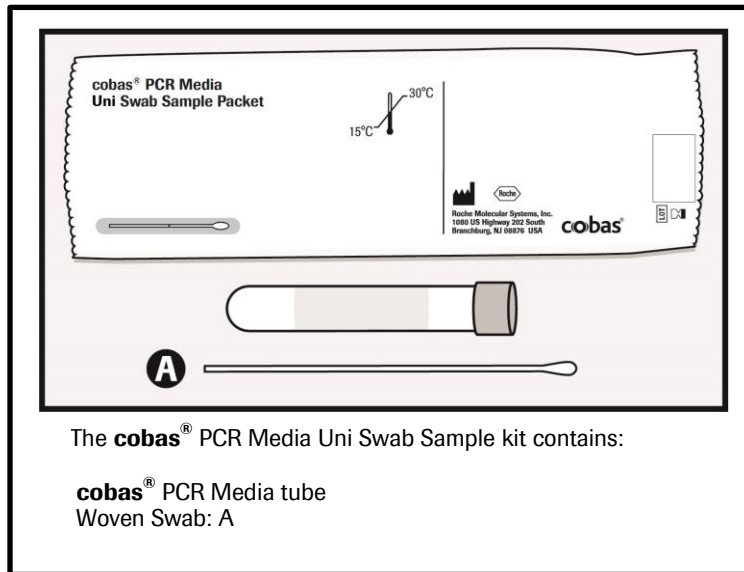


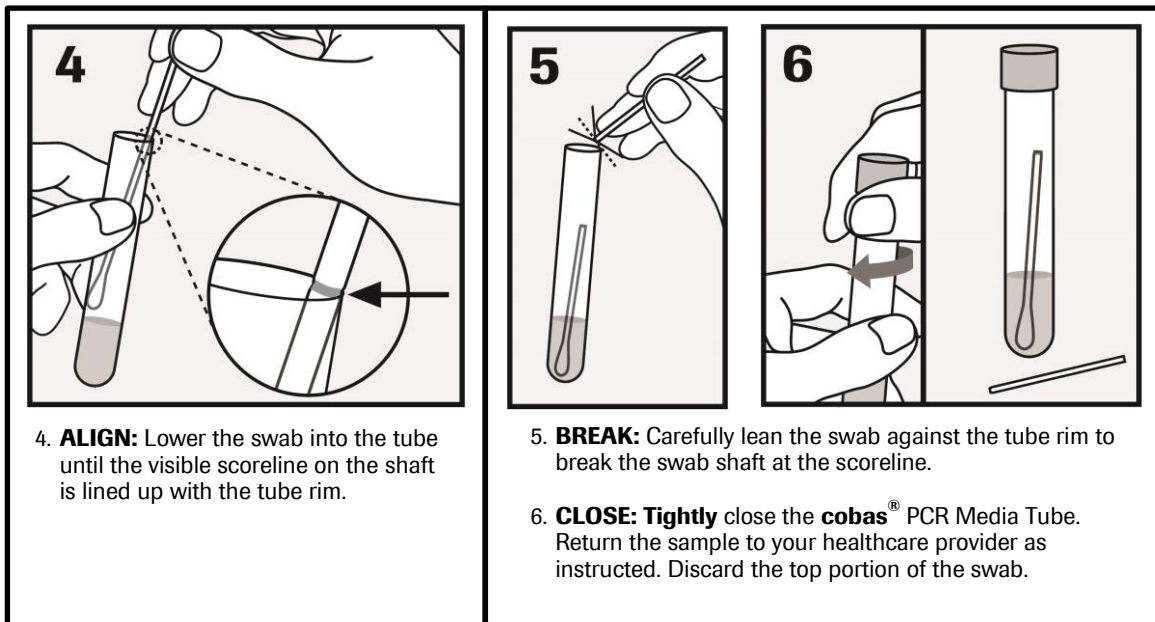
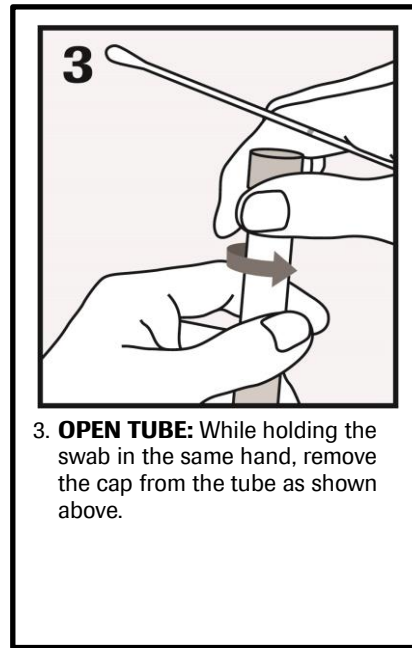
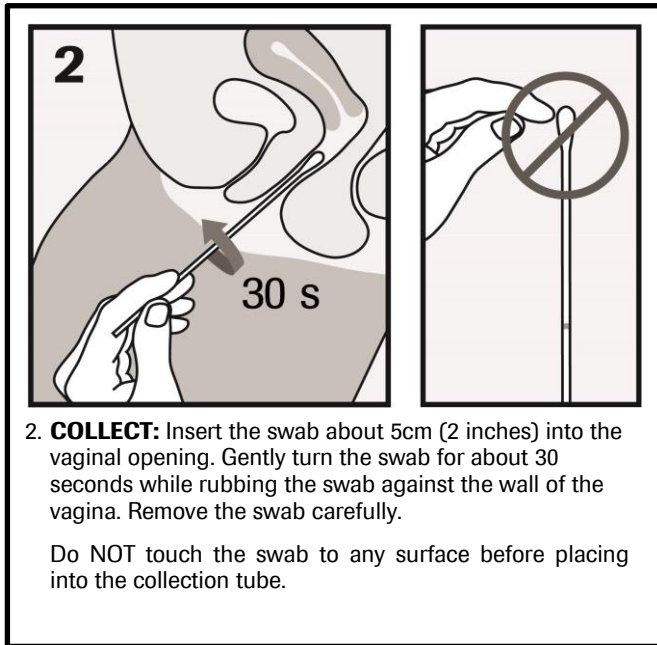
Specimen transport and storage

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- Transportation of collected specimens must comply with all applicable regulations for the transport of etiologic agents.³

Vaginal swab specimen collection – self 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 *in vitro* diagnostic medical devices.

US Customer Technical Support 1-800-526-1247

07968612001-01EN

Doc Rev. 1.0

Manufacturer and distributors

Manufactured for:



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



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

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)

Distributore in Italia:
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, SL
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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
Av. Engenheiro Billings, 1729
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6343 Rotkreuz, Switzerland

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

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