Rx Only

cobas® PCR Media Uni Swab Sample Kit

For in vitro diagnostic use

For Prescription Use Only

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 the following tests:

- **cobas**® CT/NG v2.0 Test for use on the **cobas**® 4800 System
- **cobas**® CT/NG for use on **cobas**® 6800/8800 Systems
- **cobas**® TV/MG for use on **cobas**® 6800/8800 Systems
- **cobas**® Cdiff Test for use on the **cobas**® 4800 System
- **cobas**® Cdiff Nucleic acid 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

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[b] Tris-HCl buffer	1 x 4.3 mL	 **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. Guanidinium chloride 50-01-1
Swab Envelope	1 woven swab (polyester bud)	1 swab	Not applicable

[a] Product safety labeling primarily follows EU GHS guidance

[b] Hazardous substance or mixture

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 to ensure correct sample collection.
- Care should be taken to safeguard that the swab does not break during the collection process.
- 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.
- 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 Laboratories[1] and in the CLSI Document M29-A4.[2]
- Safety Data Sheets (SDS) are available on request from your local Roche representative.
- Inform your local competent authority about any serious incidents which may occur when using this device.

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.
- Each **cobas**® PCR Media Uni Swab Sample Packet is for single-use. Do not reuse a **cobas**® PCR Media Uni Sample Packet.
- Do not use a damaged or leaking **cobas**® PCR Media tube or a damaged swab.
- 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.

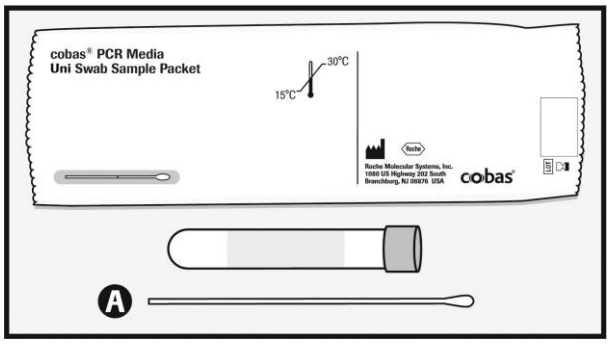
Good laboratory practice

- 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

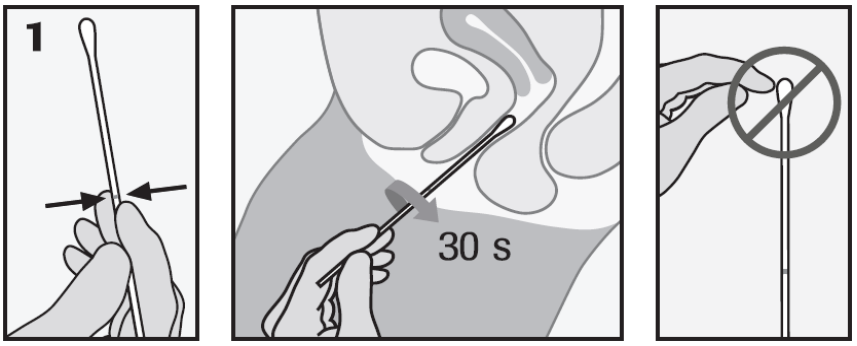
Vaginal swab specimen- clinician collection

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



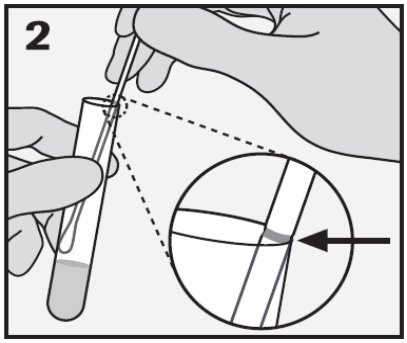
The **cobas**® PCR Media Uni Swab Sample kit contains:

cobas® PCR Media Tube
Woven Swab: A

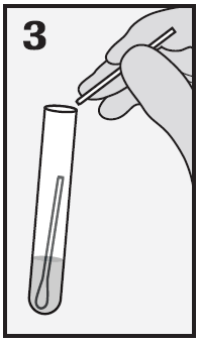


1. **COLLECT:** In one hand, hold the woven swab (Swab A) with the scoreline above your hand and insert the swab about 5 cm (2 inches) into the vaginal opening. Gently turn the swab in a clockwise direction for about 30 seconds while rubbing the swab against the walls of the vagina.

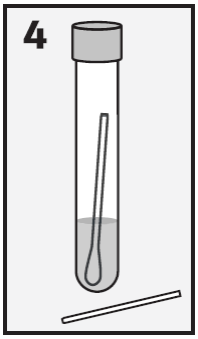
   Withdraw the swab carefully. Do not let the swab touch any surface before placing it into the collection tube.



2. **ALIGN:** Remove the cap from the **cobas**® PCR Media Tube and lower the swab specimen into the tube until the visible scoreline on the swab is aligned with the tube rim. The bud of the swab should not be submerged into the liquid prior to breaking the shaft.



3. **BREAK:** Carefully leverage the swab against the tube rim to break the swab shaft at the scoreline.



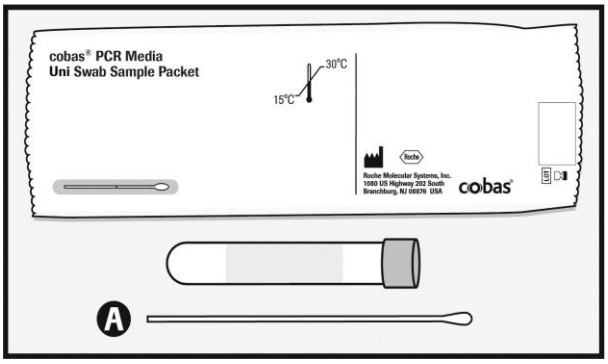
4. **CLOSE: Tightly** re-cap the **cobas**® PCR Media Tube. The specimen is now ready for transport. Discard the top portion of the **swab**.

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]

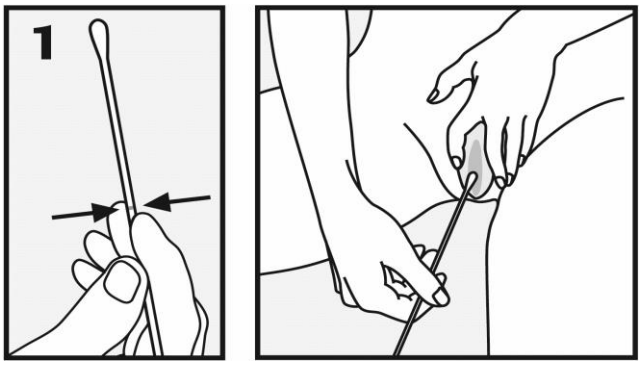
Vaginal swab specimen- self-collection in a clinical setting

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

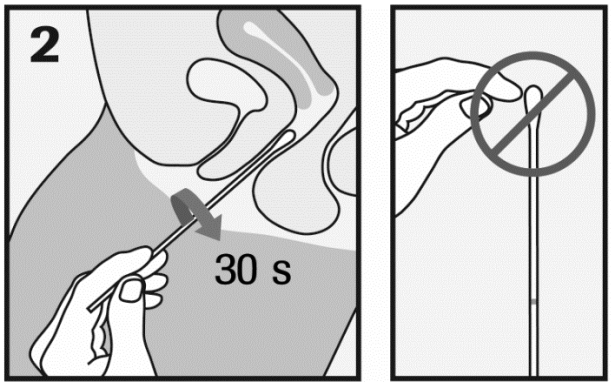


The **cobas**® PCR Media Uni Swab Sample kit contains:

cobas® PCR Media Tube
Woven Swab: A

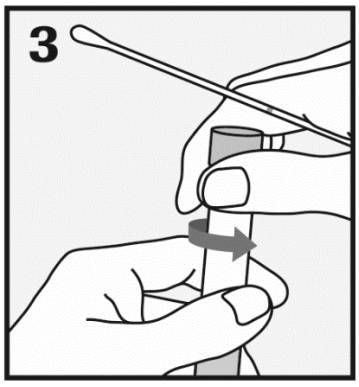


1. **POSITION:** In one hand, hold the woven swab (Swab A) with the scoreline above your hand and with the other hand separate the folds of skin around the vaginal opening (labia).

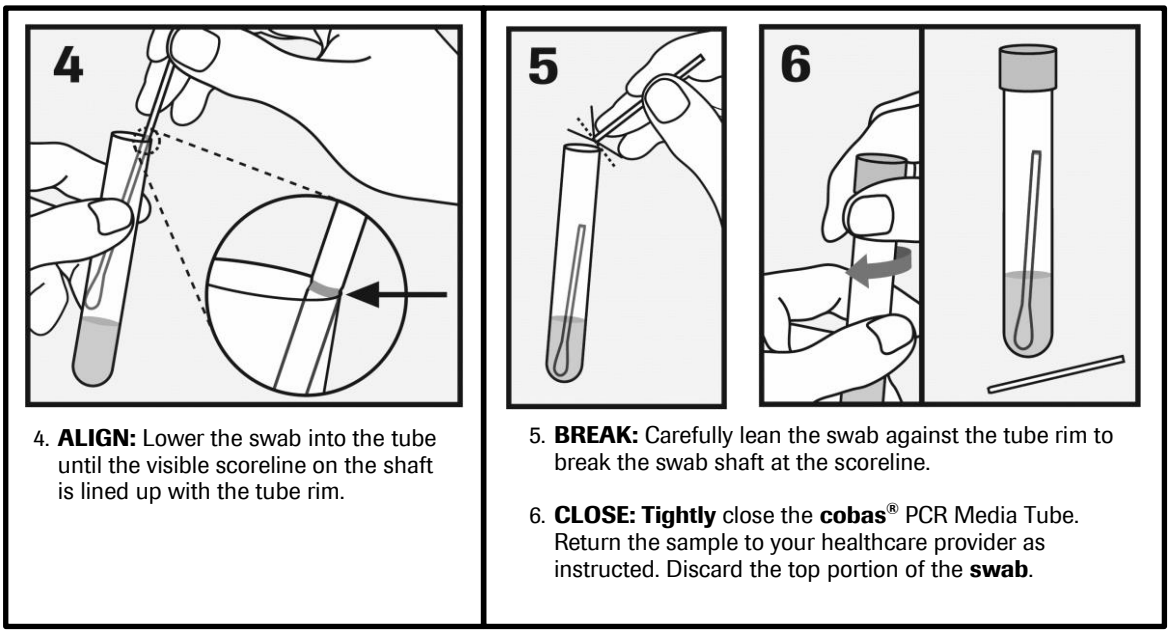


2. **COLLECT:** Insert the swab about 5 cm (2 inches) into the vaginal opening. Gently turn the swab in a clockwise direction for about 30 seconds while rubbing the swab against the wall of the vagina. Remove the swab carefully.

   Do NOT touch the swab to any surface before placing into the collection tube.



3. **OPEN TUBE:** While holding the swab in the same hand, remove the cap from the tube as shown above.



4. **ALIGN:** Lower the swab into the tube until the visible scoreline on the shaft is lined up with the tube rim.

5. **BREAK:** Carefully lean the swab against the tube rim to break the swab shaft at the scoreline.

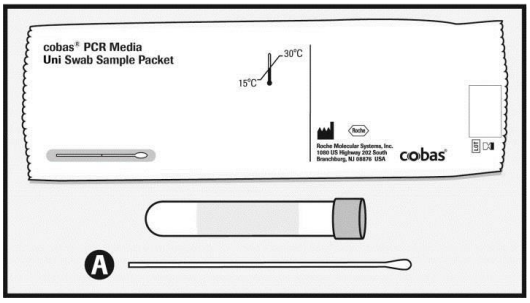
6. **CLOSE: Tightly** close the **cobas**® PCR Media Tube. Return the sample to your healthcare provider as instructed. Discard the top portion of the **swab**.

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]

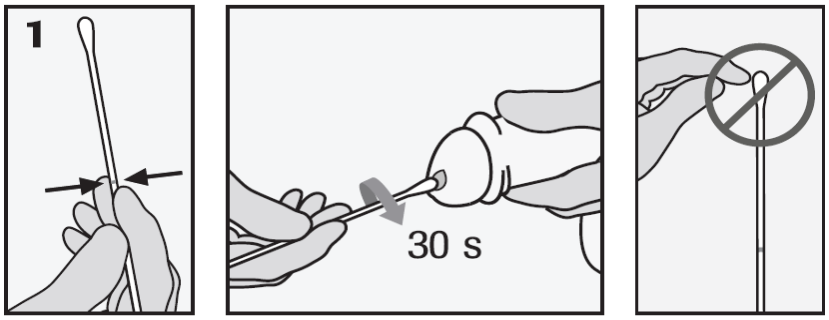
Meatal swab specimen collection- clinician or self-collected in a clinical setting

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



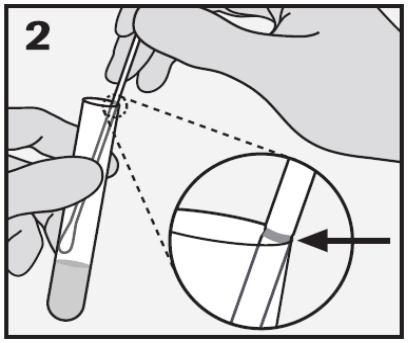
The **cobas**® PCR Media Uni Swab Sample kit contains:

cobas® PCR Media tube
Woven Swab: A

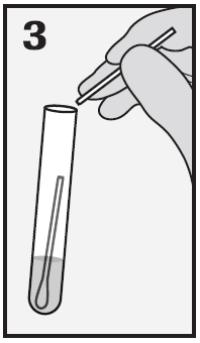


1. **COLLECT:** To collect the specimen, hold the woven swab (Swab A) with the scoreline above your hand. Turn the swab in a clockwise direction for about 30 seconds while rubbing the swab around the tip of the penis.

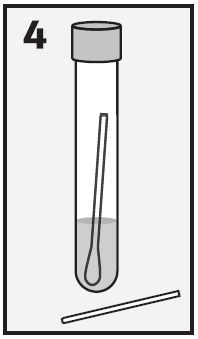
   Move the swab away carefully. Do not let the swab touch any other surface before placing it into the collection tube.



2. **ALIGN:** Remove the cap from the **cobas**® PCR Media Tube and lower the swab specimen into the tube until the visible scoreline on the swab is aligned with the tube rim.



3. **BREAK:** Carefully leverage the swab against the tube rim to break the swab shaft at the scoreline.



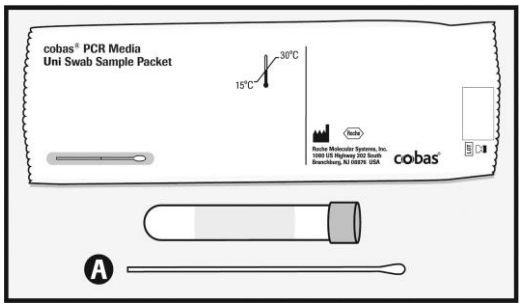
4. **CLOSE:** Tightly re-cap the **cobas**® PCR Media Tube. The specimen is now ready for transport. Discard the top portion of the **swab.**

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]

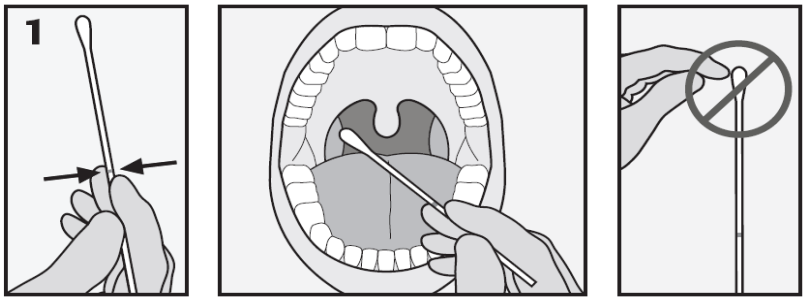
Oropharyngeal (throat) swab specimen – clinician collection

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



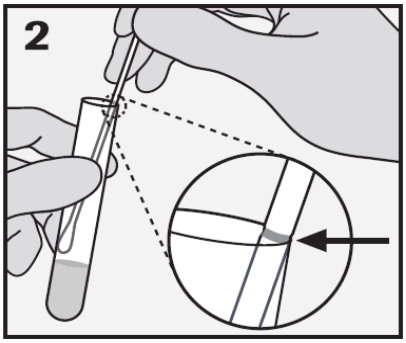
The **cobas**® PCR Media Uni Swab Sample kit contains:

cobas® PCR Media Tube
Woven Swab: A

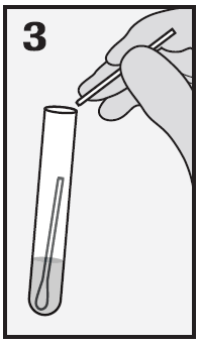


1. **COLLECT:** To collect the specimen, hold the woven swab (Swab A) with the scoreline above your hand and insert the swab into the mouth and collect the specimen from the bilateral posterior pharynx, both tonsils and the uvula.

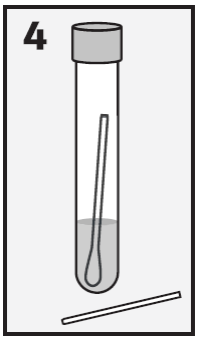
   Withdraw the swab carefully. Do not let the swab touch any surface before placing it into the collection tube.



2. **ALIGN:** Remove the cap from the **cobas**® PCR Media Tube and lower the swab specimen into the tube until the visible scoreline on the swab is aligned with the tube rim. The tip of the swab should not be submerged into the liquid prior to breaking the shaft.



3. **BREAK:** Carefully leverage the swab against the tube rim to break the swab shaft at the scoreline.



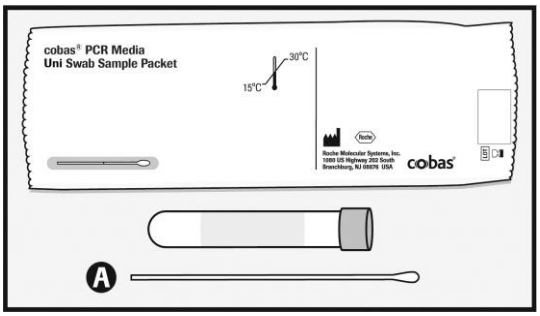
4. **CLOSE:** Tightly re-cap the **cobas**® PCR Media Tube. The specimen is now ready for transport. Discard the top portion of the **swab.**

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]

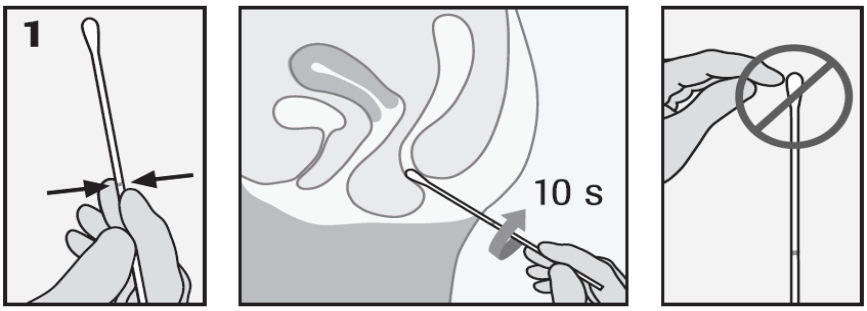
Anorectal (rectal) swab specimen – clinician collection

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



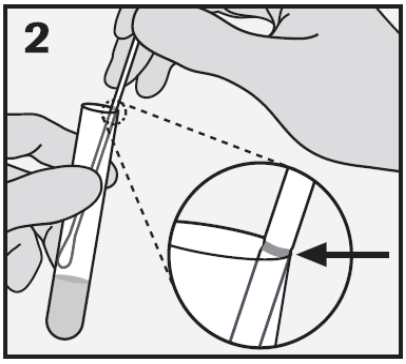
The **cobas**® PCR Media Uni Swab Sample kit contains:

cobas® PCR Media Tube
Woven Swab: A

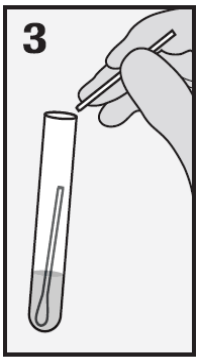


1. **COLLECT:** To collect the specimen, hold the woven swab (Swab A) with the scoreline above your hand and insert the swab about 3 to 5 cm (1–2 inches) into the anal canal. Gently turn the swab in a clockwise direction for about 5–10 seconds while running the swab against the walls of the rectum. If the swab is grossly contaminated with feces, discard and repeat the collection.

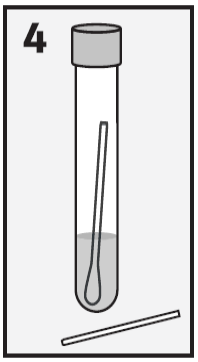
   Withdraw the swab carefully. Do not let the swab touch any surface before placing it into the collection tube.



2. **ALIGN:** Remove the cap from the **cobas**® PCR Media Tube and lower the swab specimen into the tube until the visible scoreline on the swab is aligned with the tube rim. The tip of the swab should not be submerged into the liquid prior to breaking the shaft.



3. **BREAK:** Carefully leverage the swab against the tube rim to break the swab shaft at the scoreline.



3. **CLOSE:** Tightly re-cap the **cobas**® PCR Media Tube. The specimen is now ready for transport. Discard the top portion of the **swab.**

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/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 — US Only: 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

Table 2 Manufacturer and distributor

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

Made in China

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 http://www.roche-diagnostics.us/patents

Copyright

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.

Document revision

Document Revision Information	
Doc Rev 1.0 (Mfg-CN) 12/2021	First publishing.