



Rx Only

cobas[®] PCR Media Dual Swab Sample Kit

For in vitro diagnostic use

For Prescription Use Only

cobas[®] PCR Media Dual Swab Sample Kit

P/N: 07958021190

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Intended use

The **cobas**® PCR Media Dual 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**® 5800/6800/8800 Systems
- **cobas**® TV/MG for use on **cobas**® 5800/6800/8800 Systems

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

Reagents and materials


cobas® PCR Media Dual Swab Sample Kit

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

Table 1 cobas® PCR Media Dual Swab Sample Kit

Store at 15-30°C

100 Packets (P/N 07958021190)

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	 <p>WARNING</p> <p>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</p>
Dual Swab Envelope	1 woven swab (polyester bud) 1 flocked swab (polyester Hydra Flocked Swab)	2 swabs	Not applicable

*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 to ensure correct sample collection.
- Carefully follow the instructions, as shown below.
- Care should be taken to safeguard that the swab does not break during the cleaning and/or 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 Laboratories¹ 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 Dual Swab Sample Packet is for single-use. Do not reuse a cobas® PCR Media Dual 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.

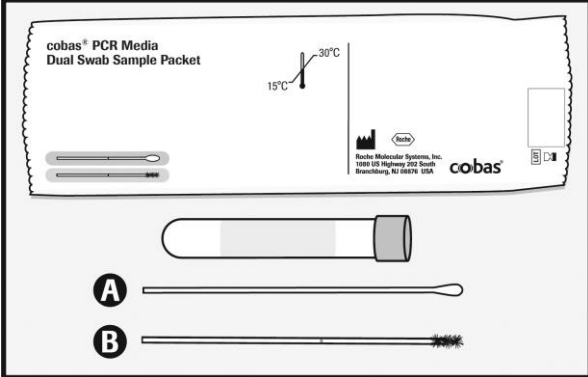
Good laboratory practice

- 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

Endocervical swab specimen collection

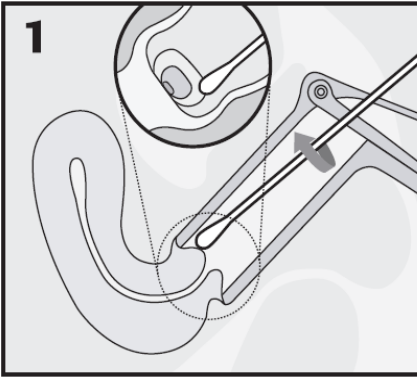
WARNING: DO NOT PRE-WET SWAB IN cobas® PCR MEDIA BEFORE COLLECTION!

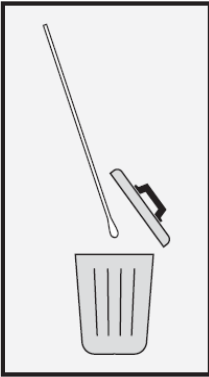


The **cobas®** PCRMedia Dual Swab Sample kit contains:

cobas® PCRMedia Tube
Woven Swab: A
Flocked Swab: B

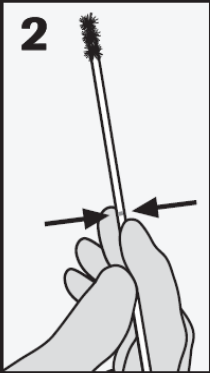
1





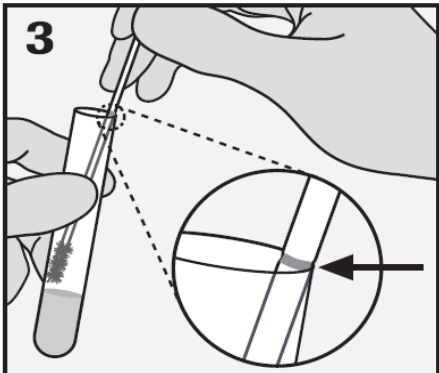
1. **CLEAN:** Using the woven swab (Swab A), remove excess mucus from the cervical os and surrounding mucosa. Discard the swab after cleaning.
NOTE: Cleaning excess mucus from the cervical os is required to ensure an adequate sample is obtained for processing.

2

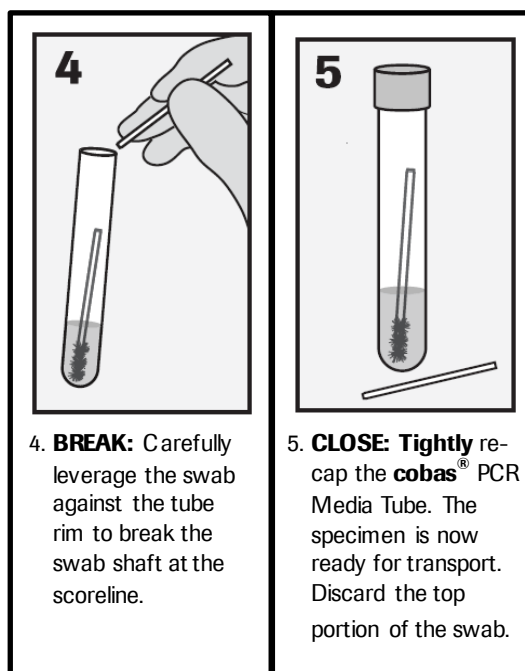


2. **COLLECT:** To collect the specimen, hold flocked swab (Swab B) with the scoreline above your hand and insert into the endocervical canal. Gently rotate the swab 5 times in one direction in the endocervical canal. Do not over-rotate. Carefully withdraw the swab, avoiding any contact with the vaginal mucosa.

3



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

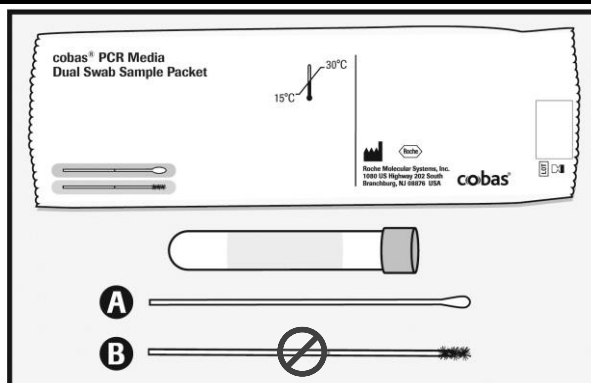


Specimen transport and storage

- 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- clinician collection

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



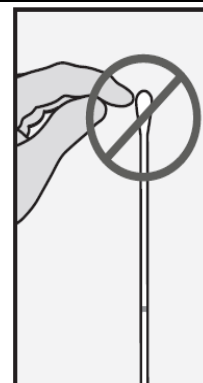
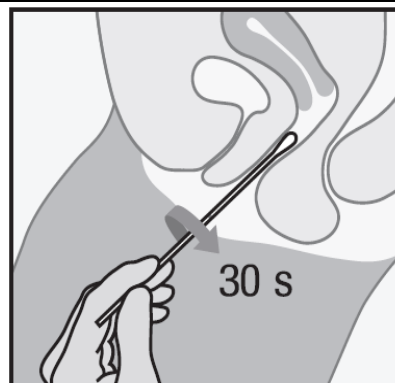
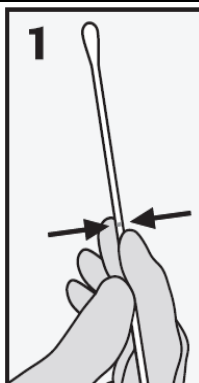
The **cobas®** PCRMedia Dual Swab Sample kit contains:

cobas® PCRMedia Tube

Woven Swab: A

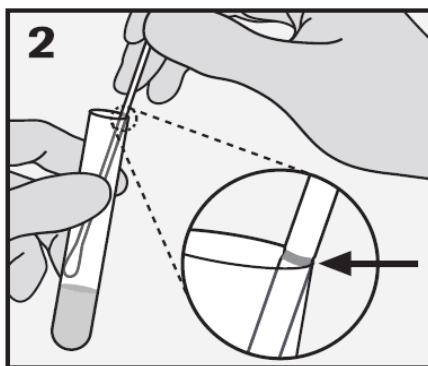
Flocked Swab: B

NOTE: Do NOT use flocked swab (Swab B) for vaginal sample collection.



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.

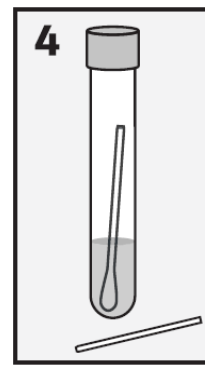
Withdraw the swab carefully. Do not let the swab touch any surface before placing it into the collection tube.



2. **ALIGN:** Remove the cap from the **cobas®** PCRMedia 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.



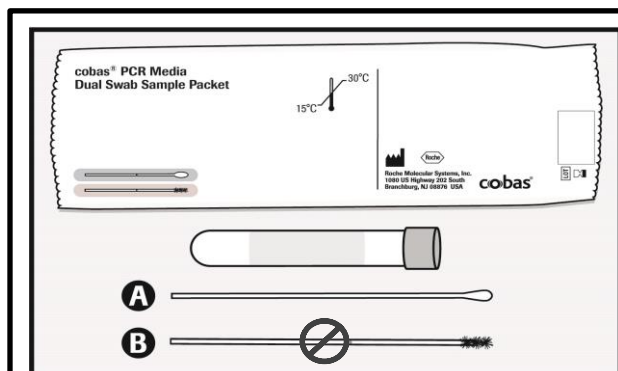
4. **CLOSE:** **Tightly** re-cap the **cobas®** PCRMedia Tube. The specimen is now ready for transport. Discard the top portion of the swab.

Specimen transport and storage

- Following specimen collection, transport and store the **cobas®** PCRMedia 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!



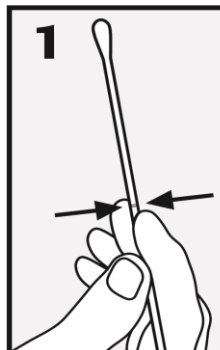
The **cobas®** PCRMedia Dual Swab Sample kit contains:

cobas® PCRMedia Tube

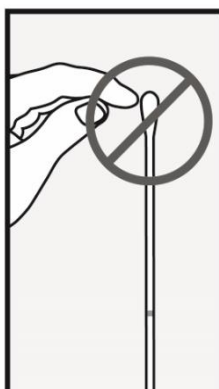
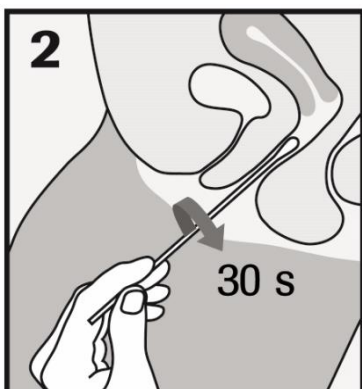
Woven Swab: A

Flocked Swab: B

NOTE: Do NOT use flocked swab (Swab B) for vaginal sample collection.

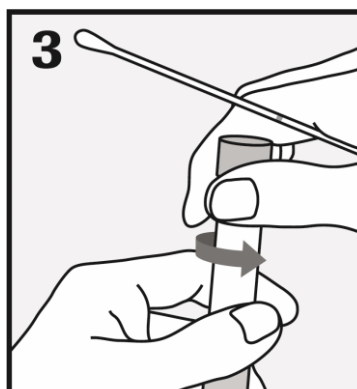


- 1. POSITION:** In one hand, hold the woven swab (Swab A) with the scoreline above your hand and with the other hand separate the folds of skin around the vaginal opening (labia).

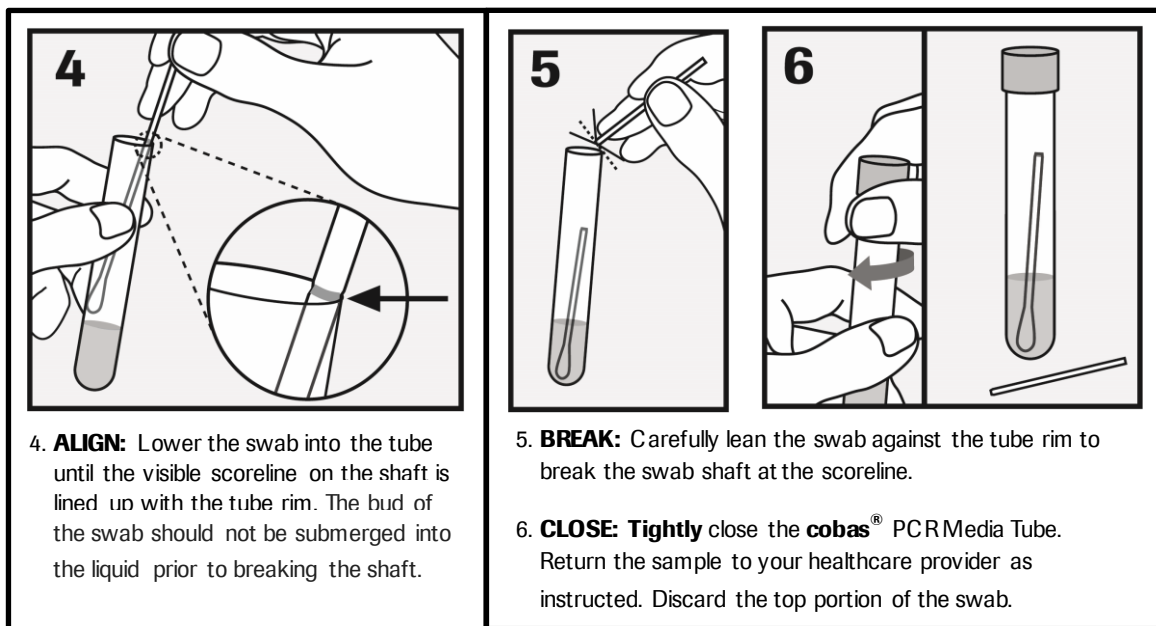


- 2. COLLECT:** Insert the swab about 5 cm (2 inches) into the vaginal opening. Gently turn the swab in a clockwise direction for about 30 seconds while rubbing the swab against the wall of the vagina. Remove the swab carefully.

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.

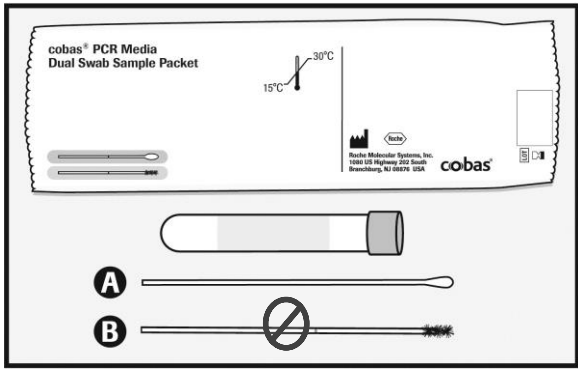


Specimen transport and storage

- Following specimen collection, transport and store the cobas® PCRMedia 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!



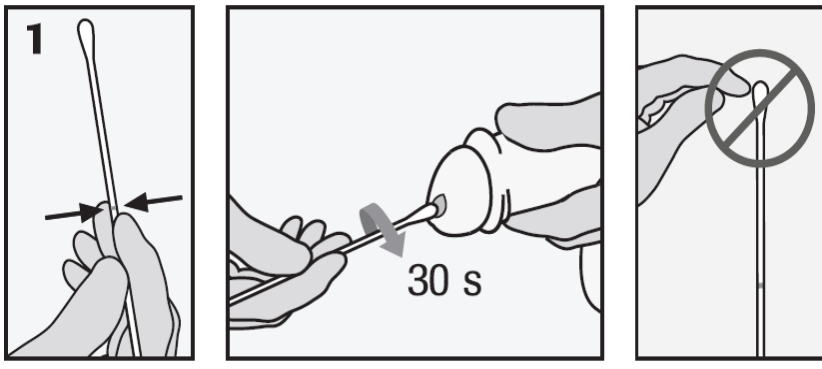
The **cobas®** PCRMedia Dual Swab Sample kit contains:

cobas® PCRMedia Tube

Woven Swab: A

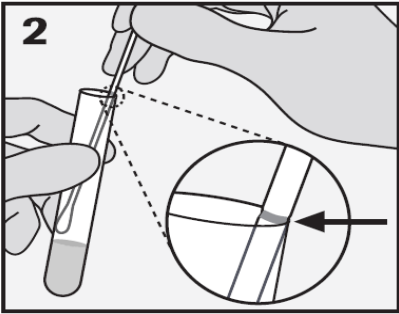
Flocked Swab: B

NOTE: Do NOT use flocked swab (Swab B) for meatal sample collection.




- 1. COLLECT:** To collect the specimen, 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.

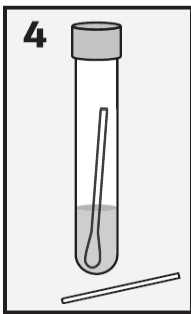
Move the swab away carefully. Do not let the swab touch any other surface before placing it into the collection tube.



- 2. ALIGN:** Remove the cap from the **cobas®** PCRMedia 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.



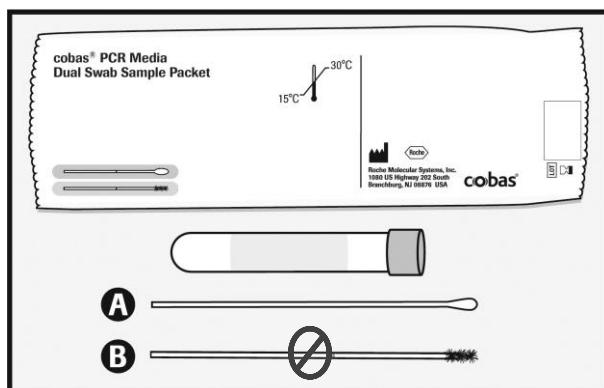
- 4. CLOSE:** Tightly re-cap the **cobas®** PCRMedia Tube. The specimen is now ready for transport. Discard the top portion of the swab.

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!



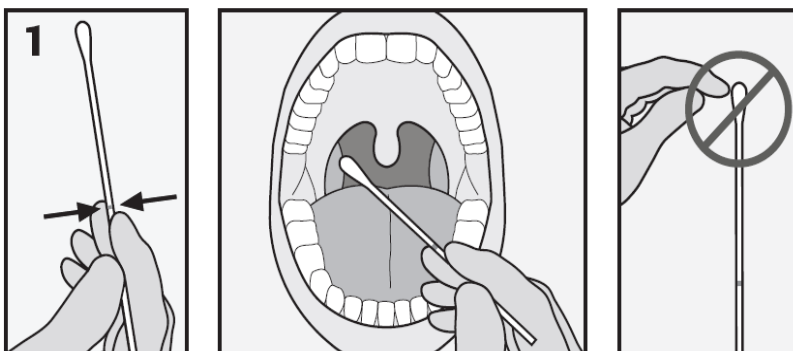
The **cobas®** PCRMedia Dual Swab Sample kit contains:

cobas® PCRMedia Tube

Woven Swab: A

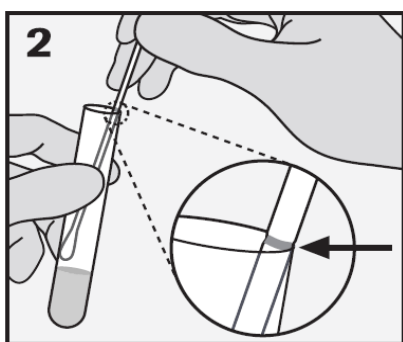
Flocked Swab: B

NOTE: Do NOT use flocked swab (Swab B) for throat sample collection.



- 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.

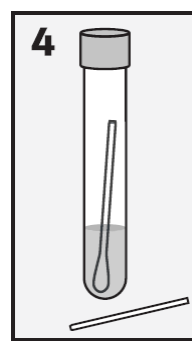
Withdraw the swab carefully. Do not let the swab touch any surface before placing it into the collection tube.



- 2. ALIGN:** Remove the cap from the **cobas®** PCRMedia 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.



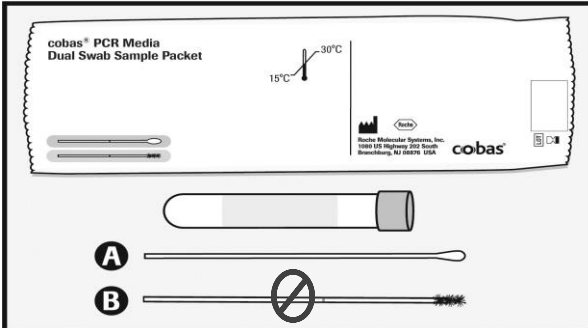
- 4. CLOSE:** Tightly re-cap the **cobas®** PCRMedia Tube. The specimen is now ready for transport. Discard the top portion of the swab.

Specimen transport and storage

- Following specimen collection, transport and store the **cobas®** PCRMedia 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®** PCRMedia Dual Swab Sample kit contains:

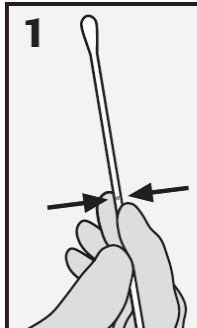
cobas® PCRMedia Tube

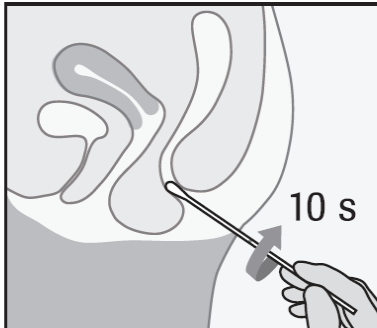
Woven Swab: A

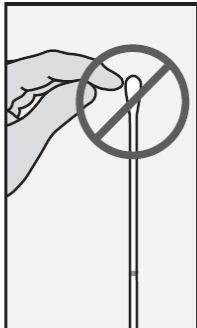
Flocked Swab: B

NOTE: Do NOT use flocked swab (Swab B) for rectal sample collection.

1



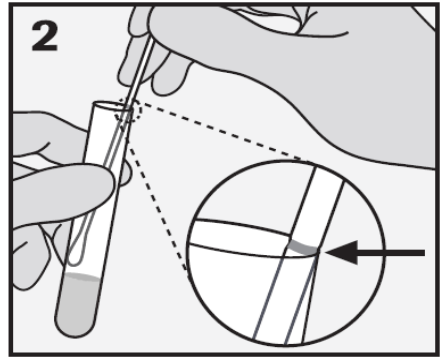




1. **COLLECT:** To collect the specimen, hold the woven swab (Swab A) with the scoreline above your hand and insert the swab about 3 to 5 cm (1-2 inches) into the anal canal. Gently turn the swab in a clockwise direction for about 5-10 seconds while running the swab against the walls of the rectum. If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



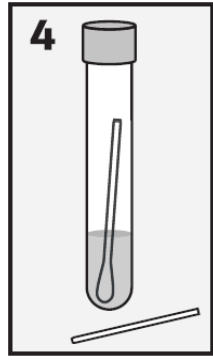
2. **ALIGN:** Remove the cap from the **cobas®** PCRMedia Tube and lower the swab specimen into the tube until the visible scoreline on the swab is aligned with the tube rim. The tip of the swab should not be submerged into the liquid prior to breaking the shaft.

3



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

4



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

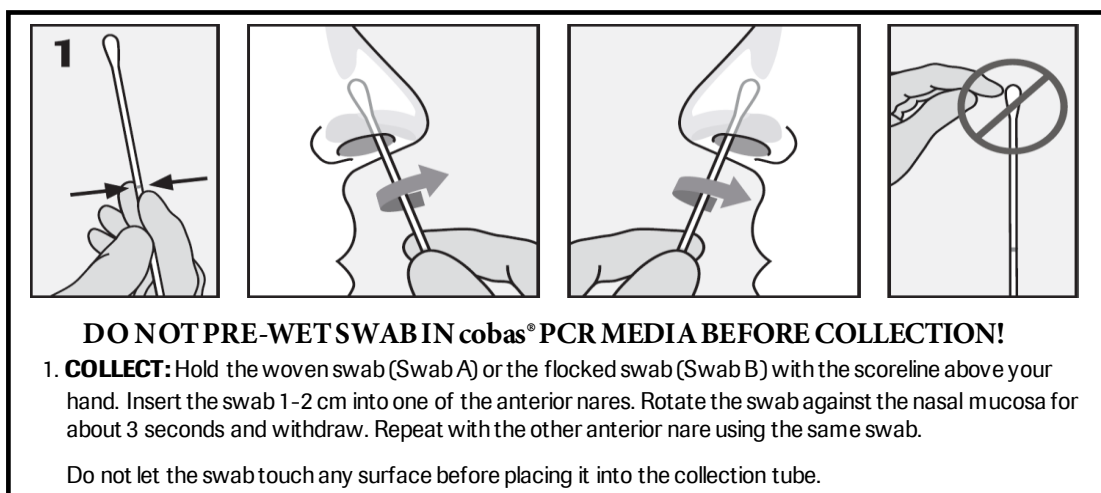
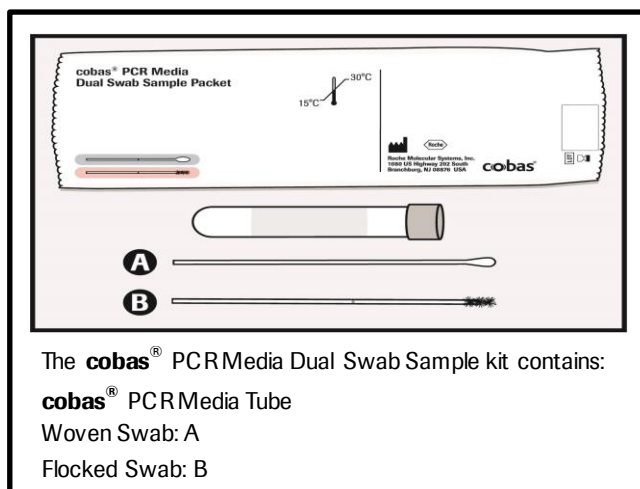
Specimen transport and storage

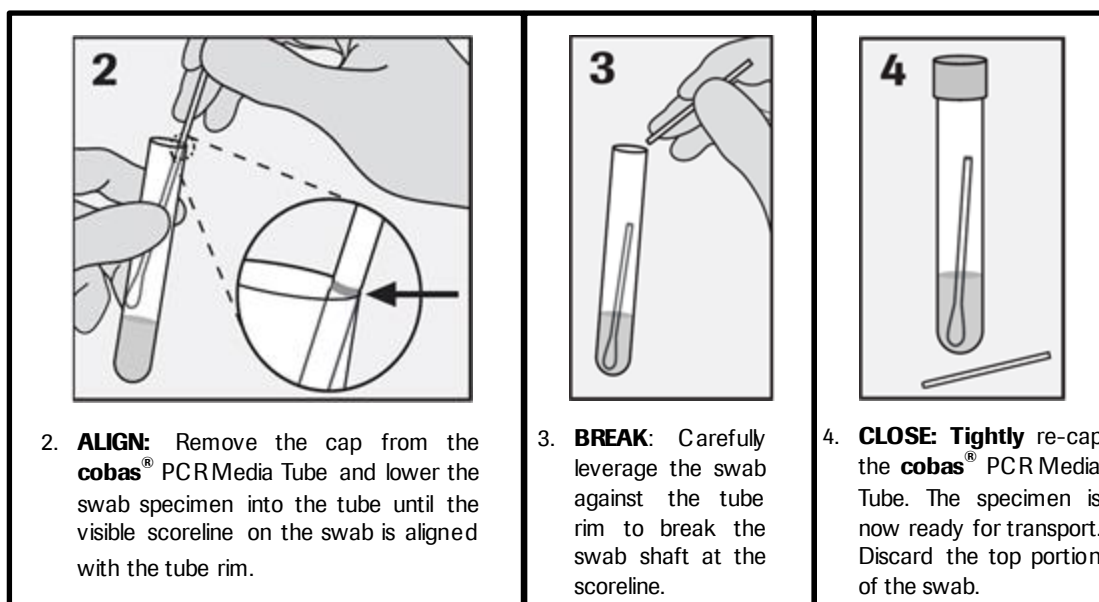
- Following specimen collection, transport and store the **cobas®** PCR Media Tube containing the collection swab at 2°C to 30°C.
- Consult the test-specific Instructions for Use for collected specimen stability claims.
- Transportation of collected specimens must comply with all applicable regulations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

Nasal (anterior nares) swab specimen collection* - clinician or self-collected on site

* The performance of the cobas® PCRMedia Dual Swab Sample Kit for use with cobas® SARS-CoV-2 Qualitative on the cobas® 6800/8800 has been evaluated in analytical studies. Clinical performance of the assay with the samples collected using the kit was not evaluated.

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 8°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



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 Data Sheet

LOT

Batch code



Biological risks

REF

Catalogue number



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



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



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



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 distributors



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>

Copyright

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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. 6.0 12/2022	<p>Added instructions for collecting a nasal specimen.</p> <p>Above nasal collection instructions added a statement justifying why the cobas® SARS-CoV-2 Qualitative for use on cobas® 6800/8800 Systems is not included in the Intended use section.</p> <p>Added Technical support section.</p> <p>Updated cobas® logo to all green on the cover page.</p> <p>Updated the harmonized symbol page.</p> <p>Updated to current economic operators.</p> <p>Updated Trademarks and patents section, including the link.</p> <p>Please contact your local Roche Representative if you have any questions.</p>
Doc Rev. 7.0 01/2023	<p>Revised to include support for the cobas® 5800 System for specimen testing.</p> <p>Updated the harmonized symbol page.</p> <p>Please contact your local Roche Representative if you have any questions.</p>