

Abbott *multi-Collect* Specimen Collection Kit

E
REF 9K12
AL1036.1

Symbol Glossary

REF	List Number	STERILE R	Sterile		Store at 15°C to 30°C		
LOT	Lot Number		Expiration Date		Manufacturer		Minimum / Maximum Urine Fill Volume
IVD	<i>In Vitro</i> Diagnostic Medical Device		Consult instructions for use		Peel Open Here		
							Do not reuse

Customer Service: 1-800-553-7042

www.abbottmolecular.com

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

NAME

Abbott *multi-Collect* Specimen Collection Kit

INTENDED USE

The Abbott *multi-Collect* Specimen Collection Kit is intended for the collection and transportation of male and female, swab and urine specimens for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* per instructions provided. Refer to the specimen collection procedure in the package insert for specimen collection instructions for specific sample types.

Self-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Abbott *multi-Collect* Specimen Collection Kit is not intended for home use.

SUMMARY AND EXPLANATION OF THE TEST

The Abbott *multi-Collect* Specimen Collection Kit contains a transfer pipette for adding approximately 3 mL of urine to the Transport Tube and an individually packaged sterile Specimen Collection Swab that is placed into the Transport Tube after swab sampling. The Transport Tube contains 1.2 mL of Specimen Transport Buffer and is used to stabilize DNA until sample preparation. The Abbott *multi-Collect* Specimen Collection Kit can be used to collect either a swab or a urine specimen.

REAGENTS

Abbott *multi-Collect* Specimen Collection Kit

50 individually-wrapped Abbott *multi-Collect* Specimen Collection Kits per box.

Each non-reusable Abbott *multi-Collect* Specimen Collection Kit contains the following:

- One Transport Tube with Solid Cap containing 1.2 mL Specimen Transport Buffer (guanidine thiocyanate in Tris buffer)
- One Sterile Specimen Collection Swab
- One disposable Transfer Pipette

MATERIALS PROVIDED

- Abbott *multi-Collect* Specimen Collection Kit
- 50 individually-wrapped Abbott *multi-Collect* Specimen Collection Kits per box.

OTHER MATERIALS REQUIRED BUT NOT PROVIDED

- Urine specimen collection cup
- Adhesive labels for sample identification information

Procedural Precautions

Read the instructions in this package insert carefully before processing samples.

WARNINGS AND PRECAUTIONS

1. **IVD FOR IN VITRO DIAGNOSTIC USE ONLY.**
2. Do not use the Abbott *multi-Collect* Specimen Collection Kit if the package is damaged, the seal is broken or if buffer has leaked from the tube. Discard unused, damaged, or leaking kits in accordance with local, state, and federal regulations.
3. Do not use the Abbott *multi-Collect* Specimen Collection Kit beyond its expiration date.
4. Wear disposable gloves while handling specimens and wash hands thoroughly afterward. Use of protective eyewear is recommended.
5. Optimal performance of the Abbott RealTime CT/NG assay requires adequate specimen collection and handling.
6. Use only the orange shaft swab provided in the Abbott *multi-Collect* Specimen Collection Kit for collecting swab specimens. The swab must remain in the Transport Tube after specimen collection. Do not place multiple swabs or a combination of swab and urine in the Transport Tube.
7. Add urine to the Transport Tube until the liquid level falls within the fill window on the tube label or else a new specimen should be collected.
8. The plastic transfer pipette provided in the *multi-Collect* Specimen Collection Kit is not sterile.
9. The presence of blood, mucus, some spermicidal agents, feminine powder sprays, and treatments for vaginal conditions such as yeast infection may interfere with nucleic acid test (NAT) based assays. The effects of other factors such as vaginal discharge, use of tampons, douching, or specimen collection variables have not been determined.
10. Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.¹⁻²
11. The Abbott *multi-Collect* Specimen Collection Kit Transport Buffer contains guanidine thiocyanate, a

chaotropic salt. Samples collected with the *multi-Collect* Specimen Collection Kit must be processed with the Abbott *mSample* Preparation System_{DNA} (4 X 24 Preps) (LN 6K11).

12. This product is not classified as dangerous as defined in 29 CFR 1910.1200 (OSHA Hazard Communication Standard). Safety data sheet (MSDS) is available upon request.

13. Do not ingest or expose skin/eyes to the Abbott *multi-Collect* Specimen Collection Kit Transport Buffer.

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.

STORAGE INSTRUCTIONS

Store unopened Abbott *multi-Collect* Specimen Collection Kit at 15°C to 30°C until the expiration date.

SPECIMEN COLLECTION PROCEDURE

Urine Specimen Collection



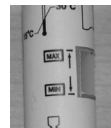
1. The patient should not have urinated for at least one hour prior to sample collection.
2. Discard specimen collection swab; it is not required for urine specimen collection.



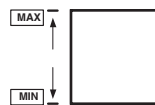
3. Using a urine specimen collection cup, the patient should collect the **first** 20 to 30 mL of voided urine (the first part of the stream).



4. Unscrew the transport tube cap, taking care not to spill the transport buffer within.
5. Handle the cap and tube carefully to avoid contamination.



6. Use the plastic transfer pipette to transfer urine from the collection cup into the transport tube until the liquid level in the tube falls within the clear fill window of the transport tube label or else a new specimen should be collected. Do not overfill. Slightly more than one full squeeze of the transfer pipette bulb may be required to transfer the necessary volume of urine specimen.
7. Recap the transport tube carefully. Ensure the cap seals tightly.



8. Label the transport tube with sample identification information, including date of collection using an adhesive label. Take care not to obscure the fill window on the transport tube.

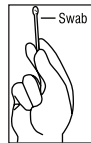
9. Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local, state, and federal regulations.¹⁻²

Self-Collected Vaginal Swab Specimen Collection

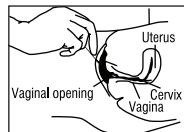
Ensure that patients read and understand the Self-Collected Vaginal Swab Instructions before providing them with an Abbott *multi-Collect Specimen Collection Kit*.

Clinician-Collected Vaginal Swab Specimen Collection

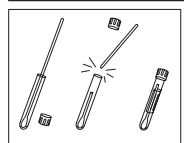
CAUTION: Do NOT expose swab to Transport Buffer prior to collection.



1. Discard disposable transfer pipette; it is not required for vaginal swab specimen collection.
2. Remove the sterile swab from the wrapper, taking care not to touch swab tip or lay it down on any surface.



3. Insert the white tip of the specimen collection swab about two inches (5 cm) into the opening of the vagina.
4. Gently rotate the swab for 15 to 30 seconds against the sides of the vagina.
5. Withdraw the swab carefully.



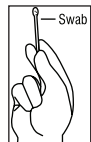
6. Handle the cap and tube carefully to avoid contamination.
7. Unscrew the transport tube cap and immediately place the specimen collection swab into the transport tube so that the white tip is down.
8. Carefully break the swab at the scored line on the shaft; use care to avoid splashing of contents.
9. Recap the transport tube. Ensure the cap seals tightly.
10. Label the transport tube with sample identification information, including date of collection using an adhesive label.

Male Urethral Swab Specimen Collection

CAUTION: Do NOT expose swab to Transport Buffer prior to collection.



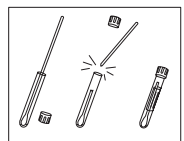
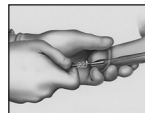
1. The patient should not have urinated for at least one hour prior to sample collection.
2. Discard disposable transfer pipette; it is not required for male urethral swab specimen collection.



3. Remove the sterile swab from the wrapper, taking care not to touch swab tip or lay it down on any surface.



4. Insert the white tip of the specimen collection swab 3/4 to 1 1/2 inches (2 to 4 cm) into the urethra.
5. Gently rotate the swab for 2 to 3 seconds to ensure adequate sampling.
6. Withdraw the swab carefully.



7. Handle the cap and tube carefully to avoid contamination.
8. Unscrew the transport tube cap and immediately place the specimen collection swab into the transport tube so that the white tip is down.
9. Carefully break the swab at the scored line on the shaft; use care to avoid splashing of contents.
10. Recap the transport tube. Ensure the cap seals tightly.
11. Label the transport tube with sample identification information, including date of collection using an adhesive label.

Urine Specimen and Swab Specimen Storage and Transport

- After collection, transport and store transport tube at 2°C to 30°C for up to 14 days.
- If longer storage is needed, store at -10°C or colder for up to 90 days.

For domestic or international shipments, specimens should be packaged and labeled in compliance with applicable state, federal, and international regulations covering the transport of clinical, diagnostic, or biological specimens. It is recommended that each tube be placed in an individual, sealable bag prior to transport.

LIMITATIONS OF THE PROCEDURE

- **FOR *IN VITRO* DIAGNOSTIC USE ONLY.**
- Optimal performance of this kit requires appropriate specimen collection, handling, preparation, and storage (refer to the **SPECIMEN COLLECTION PROCEDURE** section of this package insert).
- This kit should only be used to collect swab samples from the vagina, the male urethra, or urine specimens from males and females for testing with the Abbott RealTime CT/NG assay. Other uses of this kit have not been validated.
- The performance of Urine and Swab specimens has not been evaluated in men or women less than 18 years of age.
- The collection of samples from pregnant women using the *multi-Collect Specimen Collection Kit* should be under the guidance of an obstetrical provider or family physician.
- Vaginal swab sampling is not designed to replace cervical exams for diagnosis of female urogenital infections. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.
- Women who have symptoms suggesting pelvic inflammatory disease (PID) should not use the self-collected vaginal swab specimen as a replacement for a pelvic exam.
- The self-collected vaginal swab specimen application is limited to health care facilities where support and counseling is available to explain the procedures and precautions.

BIBLIOGRAPHY

1. Clinical and Laboratory Standards Institute. *Clinical Laboratory Waste Management: Approved Guideline-Second Edition*. NCCLS Document GP5-A2. Wayne, PA: NCCLS, 2002;22(3):1-23, 32-44.
2. US Environmental Protection Agency. *EPA Guide for Infectious Waste Management* Publication No. EPA/530-SW-86-014. Washington, DC: US Environmental Protection Agency, 1986:1-1-5-5, R1-R3, A1-A24.

The Abbott *multi-Collect Specimen Collection Kit* is manufactured for Abbott Molecular Inc. by MML Diagnostics Packaging, Inc., Troutdale, OR 97060 USA.

Abbott Molecular Inc. is the legal manufacturer of the Abbott *multi-Collect Specimen Collection Kit* Promega Corporation is the legal manufacturer of the Abbott *mSample Preparation System* _{DNA} (4 X 24 Preps)



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