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. 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.
8. Recap the transport tube carefully. Ensure the cap seals tightly.
9. 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.
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 (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
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. If using the plastic transfer pipette to transfer urine from the collection cup into the transport tube, the 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.

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 (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.
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 suggestive of 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


Abbott Molecular Inc. is the legal manufacturer of the Abbott multi-Collect Specimen Collection Kit. The 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 (4 X 24 Preps)

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