



MOB-ART-0530 Rev 6.0
HPC095R02 Date 2021.04

binx health ltd

**Vaginal Swab Specimen Collection
Kit**

USA Version

Rx Only

ENGLISH

binx health ltd - Vaginal Swab Specimen Collection Kit – USA Version – Rx Only
Information Leaflet & Instructions for Use (IFU)
Part Number (of this IFU): MOB-ART-0530

See the glossary of symbols at the end of the information leaflet

INTENDED USE

The Vaginal Swab Specimen Collection Kit is suitable for the collection, transportation and preservation of DNA in a vaginal swab sample for use with the binx *io* CT/NG Assay.

SUMMARY AND PRINCIPLES

Specimens stored and transported using the Vaginal Swab Specimen Collection Kit are intended to be processed using the *io* CT/NG (*Chlamydia trachomatis* / *Neisseria gonorrhoeae*) Assay using the binx health *io* Instrument. It is not intended to be used for the preservation and transfer of samples for any other test.

PRODUCT DESCRIPTION

The Vaginal Swab Specimen Collection Kit consists of a screw cap tube containing 2 mL of Transport and Preservation Medium and a sample collection swab which is made from copolyester with a nylon fiber flocked tip. It has a break point marked in red on the shaft in the position shown in Fig.1 below.

Fifty (50) units are contained in a shelf pack and 10 x 50 units are contained in a box. Each unit consists of one swab and one tube contained in a sterile package.

5.012.001	12 mm x 80 mm screw cap tube containing 2 mL of Transport and Preservation Medium and one co-polyester swab printed with a break point and with a flocked nylon fiber tip
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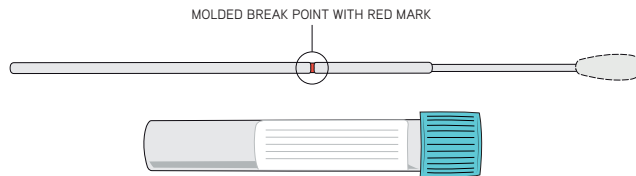


Fig. 1 Vaginal Swab Specimen Collection Kit

After the sample is collected from the patient, the molded breakpoint facilitates easy breakage of the swab applicator into the Transport and Preservation Medium tube. The action of screwing the cap onto the tube moves the end of the broken swab shaft into a funnel shaped docking receptacle in the cap. For testing, when the swab cap is unscrewed and removed, the swab applicator remains attached to the cap. This feature allows the swab to be conveniently removed from the transport tube.

REAGENTS

Guanidine thiocyanate
Tris-EDTA
HEPES
Detergent

MATERIALS REQUIRED BUT NOT INCLUDED

This sample collection kit does not require any other materials to be used. It is intended only for sample collection and transfer to the binx *io* CT/NG Cartridge for diagnostic testing on the binx *io* Instrument.

STORAGE OF THE PRODUCT

This product is ready for use and no further preparation is necessary. The product should be transported and stored in its original packaging at 5-25°C until use. Do not overheat. Do not incubate or freeze prior to use. Improper storage will result in a loss of efficacy.

LIMITATIONS

1. This product is for both professional operator (clinician) use and for patient self-collection in a clinical setting.
2. To be stored within temperature limits as labelled prior to use.
3. Once used, the sample must not be frozen.

WARNINGS AND PRECAUTIONS

1. Transport and preservation medium is not for external or internal use in humans or animals.
2. This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
3. Do not use excessive force, pressure or bending when collecting swab samples from patients as this may result in accidental breakage of the swab shaft.
4. Observe approved biohazard precautions and aseptic techniques. Transfer of the sample to the binx *io* CT/NG Cartridge for diagnostic testing on the binx *io* Instrument is to be performed in accordance with the IFU provided with the single-use Assay Kit. All specimens, and the materials used to process the specimens, should be considered potentially infectious and handled in a manner which prevents infection of laboratory personnel. Observe adequate biosafety recommendations. All biohazardous waste including specimens, containers and media should be disposed of according to local regulations after their use.
5. This product is intended for professional (clinician) use and for patient self-collection in a clinical setting, under the direction of the clinician. Specimen preparation and subsequent laboratory testing steps are to be performed by a professional operator (clinician).
6. Instructions should be read and followed carefully.
7. Not suitable for any application other than the indicated intended use.
8. The use of the Vaginal Specimen Collection Kit for the self-collection of vaginal samples in pregnant women has not been evaluated. In case of pregnancy, self-collection is not recommended, and so samples should be collected by a clinician in this case if deemed suitable by the clinician.
9. Do not use if the product is visibly damaged or has deteriorated.
10. Do not use if the Vaginal Specimen Collection Kit pouch is damaged or open.
11. Do not use the Transport and Preservation Medium to pre-moisten or pre-wet the swab prior collecting the sample or for rinsing or irrigating the sampling sites.
12. Keep the tube closed when not in use.
13. The Transport and Preservation Medium screw cap tube must be tightly closed before transporting a sample.
14. Dispose of unused reagents, waste and specimens in accordance with local regulations.
15. Avoid contact of Transport and Preservation Medium with skin and mucous membranes. If contact does occur, immediately wash with copious quantities of water.
16. Once opened, the Vaginal Swab Specimen Collection Kit must be used immediately, and unused components should not be stored individually for future use.
17. Transport and Preservation Medium contains guanidine thiocyanate. Avoid direct contact between guanidine thiocyanate and sodium hypochlorite (bleach) or other highly reactive reagents such as acids and bases. These mixtures could release noxious gases.

Contains guanidine thiocyanate.



Danger

H302 Harmful if swallowed

H314 Causes severe skin burns and eye damage

H412 Harmful to aquatic life with long lasting effects

P264 Wash hands thoroughly after handling

P273 Avoid release to the environment

P280 Wear protective gloves/protective clothing/eye protection/face protection

P301+P330+P331 IF SWALLOWED: rinse mouth. Do not induce vomiting

P303+P361+P353+P310 IF ON SKIN (or hair): remove/take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.

P305+P351+P338+P310 IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. Immediately call a POISON CENTER/doctor

EUH032 Contact with acids liberates very toxic gas

MSDS available on request from binx health Ltd, Derby Court, Epsom Square, White Horse Business Park, Trowbridge BA14 0XG, UK

PRODUCT DETERIORATION

Transport and Preservation Medium should not be used if (1) there is evidence of damage or contamination to the product, (2) there is evidence of leakage, or (3) there are other signs of deterioration.

PRODUCT STABILITY

Twelve (12) months at room temperature (5-25°C).

PERFORMANCE CHARACTERISTICS - NUCLEIC ACID PRESERVATION

The Transport and Preservation Medium preserves samples for 24 hours at ambient (5-25°C) and seven days (one week) when refrigerated (2-8°C) for use with the binx *io* CT/NG Assay. For specific information for using the Vaginal Swab Specimen Collection Kit with the binx *io* CT/NG Cartridge refer to the binx *io* User Manual and the IFU provided with the binx *io* CT/NG Cartridge.

The stability of CT and NG samples in the Vaginal Swab Specimen Collection Kit was assessed by spiking three batches of eNAT from the Vaginal Swab Specimen Collection Kits with CT Serovar F (ATCC-VR-346), and NG (strain ATCC 49226). Assessment of stability was assessed using both quantitative Polymerase Chain Reaction (qPCR) and testing using the binx *io* CT/NG Assay running on the binx *io* Instrument. Testing using qPCR confirmed that the Vaginal Swab Collection Kit preserves CT and NG for 25 hours at 25°C and for 8 days at 2-8°C. There was no statistical difference in the final concentration of CT or NG DNA in either condition when compared with samples tested at t=0. Using the *io* CT/NG Assay, all positive samples (n=20 per analyte) correctly returned CT Detected/NG Detected results after storage at 25 hours at 25°C and for 8 days at 2-8°C. 19/20 negative samples correctly returned a CT Not Detected/NG Not Detected result after storage at 25 hours at 25°C and for 8 days at 2-8°C (one negative sample, tested on day eight, after storage at 2-8°C generated a false positive result for CT/NG).

INSTRUCTIONS FOR USE

Follow this section for Patient self-collection of vaginal swab specimens – To be performed by the patient, at Point of Care, under the direction of a clinician

IMPORTANT NOTES: This procedure is intended for patient self-collection of vaginal swab specimens and must be made available and explained to the patient by the healthcare professional. The patient must read the instructions in this section carefully before self-collecting a specimen and consult her healthcare provider in case of doubts or questions about this procedure.

The use of swabs for self-collection of vaginal samples in pregnant women has not been evaluated. In the case of pregnancy, self-collection is not recommended and so samples should be collected by a clinician if deemed suitable by the clinician.

The swab shaft has a thin red-marked section to facilitate breaking of the shaft after sampling. Do not attempt to break the shaft before taking the sample. Do not attempt to bend or flex the shaft before taking the sample.

Do not use the Transport and Preservation Medium to pre-moisten or pre-wet the swab prior collecting the sample or for rinsing or irrigating the sampling sites. Do not take internally. Do not place the swab on any surface before use.

If at any time the contents of the tube are spilled on your skin, wash the affected area with copious quantities of water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water. Notify your healthcare provider if irritation develops. If the contents of the tube are spilled, request a new Vaginal Swab Specimen Collection Kit.

Wash your hands with soap and water before starting, rinse and dry.

1. Undress as necessary and get into one of the positions shown on the pictures of Fig. 2 diagram 3:
 - A. Stand with your legs apart, OR
 - B. Sit on the toilet with your legs wide apartComfortably position yourself to maintain balance during the collection procedure.
2. Open kit package. Remove the swab. Hold the swab in your hand paying attention not to touch the tip or place the swab down on a surface (Fig. 2 diagram 1).

If the tip is touched, the swab is placed on a surface, or the swab is dropped, request a new Vaginal Swab Specimen Collection Kit.

Remove the tube and set it aside.

Hold the swab in your hand as shown in Fig. 2 diagram 2, placing your thumb and forefinger covering the molded break point (red line).

3. Using your free hand, hold back the folds of skin covering the opening of your vagina as shown in Fig. 2 diagram 3.
4. Insert the swab into the vaginal opening until the fingers you are holding the swab with touch the opening of your vagina as shown in Fig. 2 diagram 4.
5. Gently rotate the swab between your fingers three times, with the swab tip touching against the sides of your vagina as shown in Fig. 2 diagram 4.
6. Withdraw the swab carefully.
7. While holding the swab with the same hand, unscrew the cap from the tube, taking care not to spill the medium.

If the contents of the tube are spilled, request a new Vaginal Swab Specimen Collection Kit.

8. Holding the tube away from your face insert the swab tip into the tube until the molded break point reaches the level of the opening of the tube as shown Fig. 2 diagram 5.
9. Break the swab off into the tube as follows:
 - a. Grasp the swab shaft at the very end with the thumb and first finger.
 - b. Lean the part of the shaft with the breaking point against the rim of the tube.
 - c. Bend the swab shaft at a 180-degree angle to break it off at the break point as shown in Fig. 2 diagram 6 taking care not to spill the medium. If needed, gently rotate the swab shaft to complete the breakage (Fig. 2 diagram 7) and discard the upper part of the swab shaft (Fig. 2 diagram 8).

If the contents of the tube are spilled, request a new Vaginal Swab Specimen Collection Kit.

10. Replace the cap on the tube and screw tightly closed (Fig. 2 diagram 9).
11. Dress yourself, wash your hands.
12. Return the collection tube to your doctor, nurse or healthcare provider.

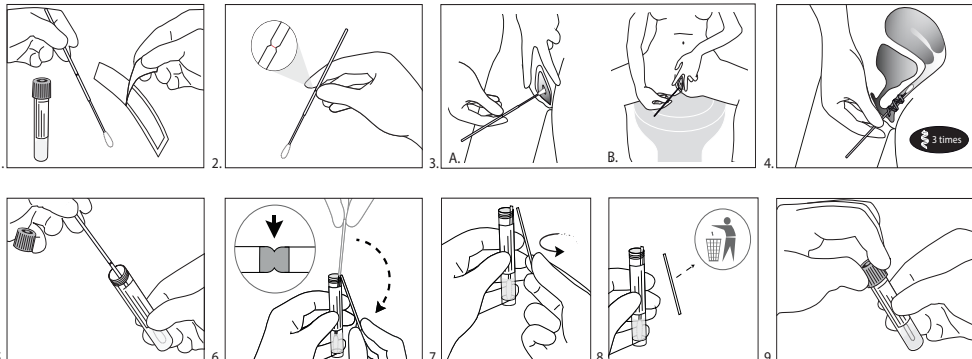


Fig. 2 Patient self-collection of vaginal swab specimens

Follow this section for Professional collection of vaginal swab specimens

Proper specimen collection from the patient is critical for the successful identification of infectious organisms. Use the kit as follows:

1. Open kit package. Remove the swab. Hold the swab in your hand paying attention to not touch the tip or place the swab down on a surface (as shown in Fig. 2 diagram 1).
2. Remove the tube. Set the tube aside.
3. Use the swab to collect the vaginal specimen from the patient. Gently rotate the swab between your fingers three times, with the swab tip touching against the sides of the vagina (as shown in Fig. 2 diagram 4).

Do not use excessive force, pressure, or bend the swab as this may result in accidental breakage of the swab shaft. Do not use the Transport or Preservation Medium for pre-moistening or pre-wetting the sampling device prior collecting the sample or for rinsing or irrigating the sampling site.

4. While holding the swab in the same hand, unscrew the cap from the tube, taking care not to spill the medium.
5. Holding the tube away from your face insert the swab tip into the tube until the molded breakpoint reaches the level of the opening of the tube (as shown in Fig. 2 diagram 5).
6. Break the swab off into the tube as follows:
 - a. Grasp the swab shaft at the very end with the thumb and first finger.
 - b. Lean the part of the shaft with the breaking point against the rim of the tube.
 - c. Bend the swab shaft at a 180-degree angle to break it off at the breakpoint (as shown in Fig. 2 diagram 6) taking care not to spill the medium. If needed, gently rotate the swab shaft to complete the breakage (as shown in Fig. 2 diagram 7) and discard the upper part of the swab shaft (as shown in Fig. 2 diagram 8).
7. Replace the cap on the tube and screw tightly closed (as shown in Fig. 2 diagram 9).

Completion of sample collection (follow for both self-collected and physician-collected)

1. Write patient information on the tube label or apply patient identification label.
2. Shake the specimen to release the sample from the swab into the preservation medium:
 - a. Hold the Transport and Preservation Medium tube by the cap making sure that it is tightly closed.
 - b. Shake the tube four (4) times downwards with rapid movements of the wrist (see Fig. 3)
3. The sample may now either be tested immediately or stored for later processing on the binx *io* Instrument.

Note: Samples may be run immediately or stored for 24 hours at room temperature (2-25°C) or stored for 7 days refrigerated (2-8°C). In any case the sample should be mixed both prior to storage AND prior to running on the binx *io* CT/NG Cartridge.

Do not allow sample to freeze at any point. Ensure that the sample is not placed close to, or in contact with, the rear of the refrigerator if stored refrigerated.

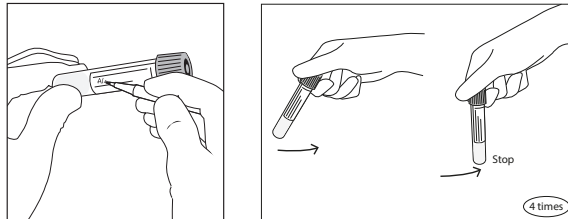


Fig. 3 Specimen preparation












Processing specimens for molecular testing with the binx *io* CT/NG Assay.

1. Hold the Transport and Preservation Medium tube by the cap making sure that it is closed tightly.
2. Shake the tube four (4) times downward with rapid movements of the wrist (see Fig. 3). *Note if the product has been stored for any duration since collection this must be performed. However, if the sample has been collected for running immediately and has just been shaken this step can be skipped.*

NOTE: Inverting the tube up and down is not recommended. if the sample appears too viscous, the specimen may remain mainly attached to the swab. In this case it is recommended to extend the shaking times to break down mucus clumps and to release the sample from the swab. If the sample is foamy, it is recommended to wait for foam to disperse before continuing.

3. Unscrew the cap and use the Transfer Pipet provided with the binx *io* single-use Assay Kit to transfer 500 µL to the Cartridge, following the IFU provided.
4. Close the tube using the Cap. Store or dispose of the sample as required.

Glossary of Symbols

Symbol	Meaning
	Manufacturer
	Sterilized using irradiation
	Do not reuse
	Catalog number
	Temperature limitation
	Use-by date
	Consult Instructions for Use
	Batch code (Lot)
	Contains sufficient for <n> tests
	Do not use if package is damaged
	Caution



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