



MOB-ART-0540 Rev 5.0
HPC096R01 Date 2021.04

binx health ltd

**Male Urine Specimen
Collection Kit**

USA Version

Rx Only



ENGLISH

**binx health ltd – Male Urine Specimen Collection Kit – USA Version – Rx Only
Information Leaflet & Instructions for Use (IFU)
Part Number (of this IFU): MOB-ART-0540**

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

INTENDED USE

The Male Urine Specimen Collection Kit is suitable for the collection, transportation and preservation of DNA in a male urine sample for use with the binx *io* CT/NG Assay.

SUMMARY AND PRINCIPLES

Specimens stored and transported using the Male Urine 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 Male Urine Specimen Collection Kit consists of a screw cap tube containing 0.444 mL of Transport and Preservation Medium and a single 2 mL Transfer Pipet.

Fifty (50) units are contained in a shelf pack and 10 x 50 units are contained in a box. Each unit consists of a sterile package containing two components: a labeled polypropylene screw-cap tube with conical shaped bottom containing 0.444 mL of Transport and Preservation Medium and a 2 mL Transfer Pipet.

5.002.001	12 mm x 80 mm screw cap tube containing a nominal volume of 0.444 mL of Transport and Preservation Medium and one 2 mL Transfer Pipet.
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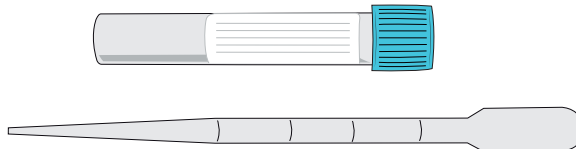


Fig. 1 Male Urine Specimen Collection Kit

REAGENTS

Guanidine thiocyanate
Tris-EDTA
HEPES
Detergent

MATERIALS REQUIRED BUT NOT INCLUDED

Urine cup for collection of first-catch urine (20-30 mL)

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 professional operator (clinician) use.
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. 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 CT/NG 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.
4. This product is intended for professional (clinician) use.
5. Instructions should be read and followed carefully.
6. Not suitable for any application other than the indicated intended use.
7. Do not use if the product is visibly damaged or has deteriorated.
8. Do not use if the Male Urine Specimen Collection Kit pouch is damaged or open.
9. Do not use the same Male Urine Specimen Collection Kit for more than one patient.
10. Keep the tube closed when not in use.
11. The Transport and Preservation Medium screw cap tube must be tightly closed before transporting a sample.
12. Dispose of unused reagents, waste and specimens in accordance with local regulations.
13. Avoid contact of Transport and Preservation Medium with skin and mucous membranes. If contact does occur, immediately wash with copious quantities of water.
14. Once opened, the Male Urine Specimen Collection Kit must be used immediately, and unused components should not be stored individually for future use.
15. 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 Male Urine 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 Male Urine Specimen Collection Kit was assessed using three lots of Male Urine Specimen Collection Kits within expiry and three lots beyond expiry (which had been previously stored at either 4°C or 30°C - beyond the extremes of the labeled storage conditions). Collection Kits were spiked with CT Serovar F (ATCC-VR-346), and NG (strain ATCC 49226). Stability was assessed using both quantitative Polymerase Chain Reaction (qPCR) and the binx *io* CT/NG Assay running on the binx *io* Instrument. qPCR confirmed that the Male Urine Specimen Collection Kit preserves CT and NG for 25 hours at 25°C and for 8 days at 2-8°C. Using the *io* CT/NG Assay, all positive and negative samples correctly returned CT Detected/NG Detected or CT Not Detected/NG Not Detected results, respectively, following storage at 25 hours at 25°C and for 8 days at 2-8°C for all lots tested.

INSTRUCTIONS FOR USE

Follow this section for collection of male urine specimens – to be performed by professional operator (clinician)

IMPORTANT NOTES: 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, use a new Male Urine Specimen Collection Kit. It is essential to add the urine to the transport and preservation medium tube within 15 minutes of urine collection.

1. Ask the male patient to collect the first 20 to 30 mL of first-catch urine (the first part of the stream) into a urine cup (not supplied with the kit).
2. Open the Male Urine Specimen Collection Kit pouch. Remove the Transport and Preservation Medium tube. See Fig. 2 panel A.
3. Hold the Transfer Pipet by the bulb making sure not to touch the tip. Do not lay the Transfer Pipet down on a surface. See Fig. 2 panel B.
4. Unscrew and remove the cap from the transport medium tube making sure not to spill the medium.
5. Within 15 minutes of urination, transfer two pipets' worth of male urine (approximately 4 mL) from the urine cup into the collection tube as follows:
6. Use the Transfer Pipet provided with the kit. The Transfer Pipet has a scale with a mark every 0.5 mL. Squeeze the bulb in order to draw up ~2 mL of male urine from the urine cup. See Fig. 2 panel C.
7. Move the tip of the pipet into the collection tube and squeeze the bulb to expel the male urine. See Fig. 2 panel D.
8. Repeat steps shown in Fig. 2 panels C and D to transfer an additional ~2 mL of male urine into the collection tube so that a total of ~4 mL has been transferred.
9. Hold the tube vertically upright and check that the level is now between the "maximum" and "minimum" indicator lines on the tube. See Fig. 2 panel E.
10. Replace the cap on the tube and close tightly. See Fig. 2 panel F.

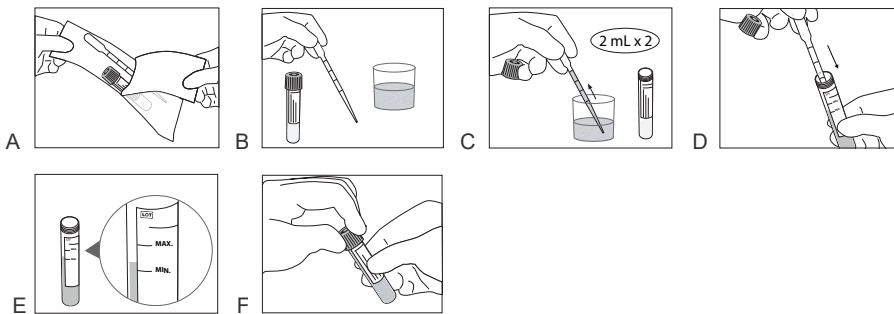


Fig. 2 Collection and preparation of male urine specimens

Completion of sample collection

1. Write patient information on the tube label or apply patient identification label. See Fig 3 panel A.
2. Ensure the Preservation Medium tube cap is tightly closed.
3. Invert the tube four (4) times (see Fig. 3, panels B/C) to ensure the urine and preservation medium are fully mixed.
4. The sample may now either be tested immediately or stored for later processing on the binx *io* Instrument.

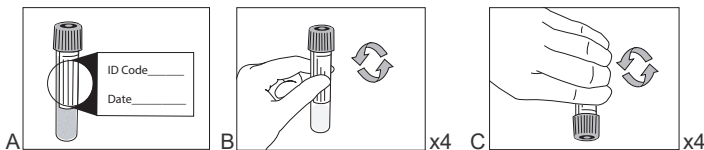


Fig. 3 Completion of sample collection

Notes:

- *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).*
- *It is essential that the sample is 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.*

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












1. Ensure the Preservation Medium tube cap is tightly closed.
2. Invert the tube four (4) times (see Fig. 3) to ensure the sample is fully mixed.

NOTE: Shaking the tube up and down is not recommended. If the sample is very foamy, it is recommended to wait for the 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.

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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



Made by Copan Italia SPA (Italy) for binx health ltd

binx health ltd
Derby Court, Epsom Square,
White Horse Business Park, Trowbridge,
Wiltshire, BA14 0XG United Kingdom
Tel: +1 844-MYBINX-1 (+1 844-692-4691)
E-mail: support@mybinxhealth.com
Website: www.mybinxhealth.com

