



# LBM<sup>®</sup> UriSponge<sup>™</sup>

Package insert and How-to-use guide

IVD



ENGLISH
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## Copan UriSponge™ - Urine Collection, Transport and Preservation System Product Insert & How to Use Guide

### INTENDED USE

Copan UriSponge™ - Urine Collection, Transport and Preservation System is intended for the collection, transport and preservation of urine specimens from the collection site to the testing laboratory. In the laboratory, UriSponge™ specimens are processed using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.

### SUMMARY AND PRINCIPLES

Bacteria quantification of clean-voided midstream collected urine is widely used to evaluate urinary tract infections (1). The maintenance of the bacterial load in urine samples depends on many factors including the type and concentration of the microorganisms, duration of transport and storage temperature (2). The UriSponge™ device incorporates preservative substances (urine maintenance formula) onto the applicator sponge within a conical bottom, screw-cap tube, which sustains the viability of clinically important organisms during transport for up to 48 hours at 2–25 °C.

### PRESERVATIVE

Copan UriSponge™ incorporates preservative substances (urine maintenance formula) onto the applicator sponge. The concentration of preservative per milliliter of urine sample collected with UriSponge™ device is estimated as follow:

Boric Acid	7.3 mg/ml
Sodium Formate	2.4 mg/ml

### PRECAUTIONS

1. For In Vitro Diagnostic Use only.
2. For professional use only. Use UriSponge™ in accordance with the Package Insert.
3. Do not use if the package or tube is open, there is evidence of damage, deterioration, contamination or the expiration date has passed.
4. Do not re-sterilize. Do not re-pack.
5. Not suitable for the recovery of fastidious microorganisms, e.g. anaerobes, viruses, chlamydiae, mycoplasmas, ureaplasmas trichomonas, in culture.
6. Not suitable for collection of specimens for microscopic and macroscopic examination.
7. Use of this device in association with diagnostic kits and/or instrumentation should be validated prior to use.
8. Wear protective gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe appropriate CDC Biosafety recommendations. After use, tubes must be disposed of according to laboratory regulations for infectious waste (7,8,9).

### DEVICE STORAGE

Store in the original packaging at 2–25 °C until used. Do not freeze prior to use.

### DEVICE DESCRIPTION / HOW SUPPLIED

Copan UriSponge™ - Collection, Transport and Preservation system is ready-to-use. Product descriptions and packaging configurations are listed in Table 1.

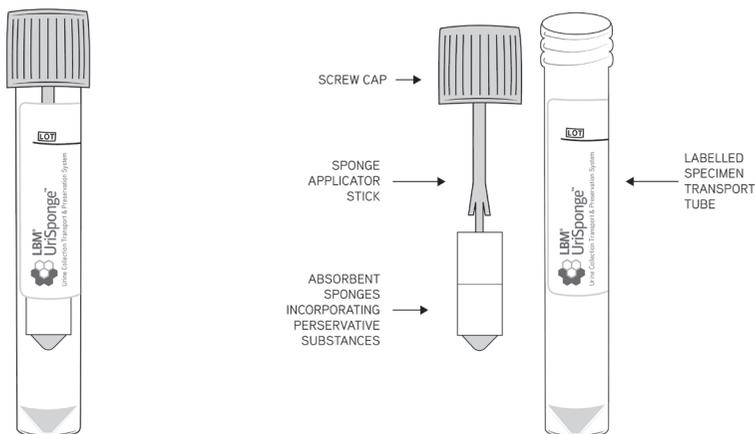


Figure 1: UriSponge™ device

Figure 2: UriSponge™ components

Table 1. UriSponge™ Description and Packaging Configurations

	<b>Copan UriSponge™ - Product Descriptions</b>	<b>Pack Size</b>	<b>Urine Sample Volumes</b>
8C023S01.A	Single use pre-pierced pack containing mini size sterile plastic tube with screw cap (80 mm length x 12 mm diameter). Inside the tube the cap holds a sponge applicator with two cylinders of hydrophilic polyurethane foam incorporating preservative substances.	50 devices in single pouch per pack 10 x 50 devices per box	Absorbed urine volume from sponges will be approximately 1,5 ml. Released volume from saturated sponges by centrifugation at 104 g will be approximately 1,0 ml.
8C021S01.A	Single use pre-pierced pack containing regular size sterile plastic tube with screw cap (100 mm length x 16 mm diameter). Inside the tube the cap holds a sponge applicator with three cylinders of hydrophilic polyurethane foam incorporating preservative substances.	30 devices in single pouch per pack 10 x 30 devices per box	Absorbed urine volume from sponges will be approximately 3,2 ml. Released volume from saturated sponges by centrifugation at 149 g will be approximately 2,9 ml.
8C022S100.A	Plastic sealed bag containing 100 pieces of single use devices composed of mini size sterile plastic tube with screw cap (80 mm length x 12 mm diameter). Inside the tube the cap holds a sponge applicator with two cylinders of hydrophilic polyurethane foam incorporating preservative substances.	100 devices per shelf pack 100 x 5 devices per box	Absorbed urine volume from sponges will be approximately 1,5 ml. Released volume from saturated sponges by centrifugation at 104 g will be approximately 1,0 ml.
8C020S100.A	Plastic sealed bag containing 100 pieces of single use devices composed of regular size sterile plastic tube with screw cap (100 mm length x 16 mm diameter). Inside the tube the cap holds a sponge applicator with three cylinders of hydrophilic polyurethane foam incorporating preservative substances.	100 devices per shelf pack 100 x 5 devices per box	Absorbed urine volume from sponges will be approximately 3,2 ml. Released volume from saturated sponges by centrifugation at 149 g will be approximately 2,9 ml.

**MATERIALS REQUIRED BUT NOT SUPPLIED**

Sterile urine collection cup and appropriate materials for the isolation and culture of uropathogenic bacteria and yeast, e.g. culture media and incubation systems are not provided. Refer to laboratory reference manuals for recommended procedures for the culture and identification of uropathogenic bacteria and yeasts from clinical samples (1,4).

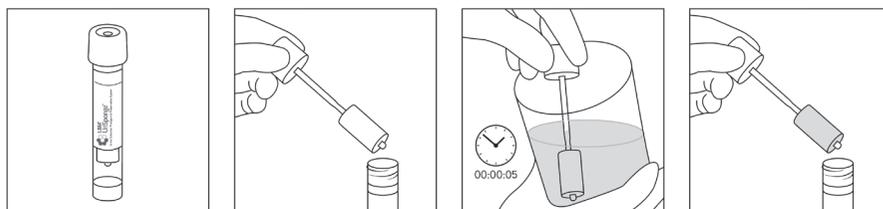
## INSTRUCTIONS FOR USE

### Specimen Collection and Transport with UriSponge™

Proper specimen collection from the patient is critical for successful isolation and identification of infectious organisms. Specimens obtained for assessment of urinary tract pathogens should be collected and handled following published manuals and guidelines (1, 2, 3,4).

1. Obtain a clean-catch urine sample from the midstream portion into a sterile container.
2. Open the UriSponge™ tube and, holding by the cap, dip the sponge applicator into the urine sample. Submerge the sponges for 5 seconds. The polyurethane sponges are extremely hydrophilic and spontaneously absorb urine.
3. Remove the sponge applicator from the urine sample and return it to the UriSponge™ tube. See Figure 3. Do not add urine to the tube other than the urine spontaneously absorbed by the sponge.
4. Screw the cap to securely close the container.
5. Label and transport UriSponge™ specimens in accordance with institutional, local, state, and federal requirements (6).
6. Immediately transfer UriSponge™ specimen(s) to the laboratory, preferably within 2 hours of collection (20). If immediate delivery or processing is delayed UriSponge™ specimens may be refrigerated at 2-8 °C or stored at room temperature (20-25 °C) and processed within 48 hours.

Figure 3: Transfer of urine sample to UriSponge™ device.



### Testing UriSponge™ Specimens for Culture in the Laboratory

1. UriSponge™ specimens should be processed immediately upon receipt and within 48 hours of collection.
2. UriSponge™ tubes may be centrifuged to extract the urine from the sponge. Centrifuge at 104 g for the mini size tube and 149 g for the regular size tube for 3 seconds in a swing-out rotor centrifuge. UriSponge™ may be re-centrifuged as needed. Alternatively, the specimen can be manually extracted from the sponge by shaking the device down three times using quick, sharp, downward wrist motions.
3. Using aseptic technique, unscrew the cap and remove the sponge applicator. Gently mix the content of the tube.
4. Follow laboratory internal Standard Operating Procedures (SOPs) for inoculating the urine sample from the tube onto culture media or refer to published microbiology manuals and guidelines (1,4).

### LIMITATIONS

- Condition, timing and volume of specimen collected for culture are significant variables in obtaining reliable culture results. Follow recommended guidelines for specimen collection (1, 2, 3, 4).
- The microbial load in urine from a given patient may be influenced by the time of collection and fluid intake. Symptomatic patients may have counts below  $10^5$  microorganism/ml if specimens are collected late in the day or if diuresis is occurring (10).
- The sponge preservatives will not inactivate antibiotics.

### QUALITY CONTROL

UriSponge™ is verified to maintain viability after storage at 2-8 °C (refrigerated) and 20–25 °C (room temperature) for up to 48 hours using the organisms recommended by the Clinical and Laboratory Standards Institute (CLSI) M40-A2 (5).

Procedures for quality control of microbiology transport devices should be conducted using testing methods described in CLSI M40-A2 (4). If aberrant quality control results are noted, patient results should not be reported.

### PERFORMANCE CHARACTERISTICS

The performance of UriSponge™ has been verified per CLSI M40-A2 for "Urine Culture Containers With Preservative" using a known concentration of each organism suspended in filtered synthetic urine. All organisms were ATCC® derived and were maintained in accordance with the manufacturer's instructions.

### Microorganism recovery (viability) study

The ability of UriSponge™ to maintain viability of urinary tract microorganisms was assessed after storage at refrigerated and controlled room

temperature for 24 and 48 hours. Recovery of each organism on non-selective agar media plates after being held under the challenge conditions was verified to remain within 1 log<sub>10</sub> of the initial concentration. See Table 2.

Table 2. Performance of UriSponge™ in maintaining the viability of urinary tract microorganisms

Recovery of Urine Culture Organisms in UriSponge™ per CLSI M40-A2					
Organism	Holding Temperature	T=0	T=24	T=48	T=48 hours Log reduction (-) or Log increase (+)
<b>Average CFU recovered N=9 (from three lots)</b>					
<i>C. albicans</i> (ATCC® 24433)	2-6 °C	7,37 x 10 <sup>2</sup>	4,70 x 10 <sup>2</sup>	3,92 x 10 <sup>2</sup>	-0,27
	20-24 °C	7,37 x 10 <sup>2</sup>	3,79 x 10 <sup>2</sup>	3,11 x 10 <sup>2</sup>	-0,37
<i>E. coli</i> (ATCC® 25922)	2-6 °C	2,15 x 10 <sup>3</sup>	1,78 x 10 <sup>3</sup>	1,16 x 10 <sup>3</sup>	-0,28
	20-24 °C	2,15 x 10 <sup>3</sup>	1,22 x 10 <sup>3</sup>	4,26 x 10 <sup>2</sup>	-0,71
<i>E. faecalis</i> (ATCC® 29212)	2-6 °C	2,11 x 10 <sup>3</sup>	1,64 x 10 <sup>3</sup>	1,72 x 10 <sup>3</sup>	-0,09
	20-24 °C	2,11 x 10 <sup>3</sup>	1,18 x 10 <sup>3</sup>	1,04 x 10 <sup>3</sup>	-0,31
<i>P. aeruginosa</i> (ATCC® 27853)	2-6 °C	2,40 x 10 <sup>3</sup>	1,96 x 10 <sup>3</sup>	1,70 x 10 <sup>3</sup>	-0,15
	20-24 °C	2,40 x 10 <sup>3</sup>	1,34 x 10 <sup>3</sup>	5,31 x 10 <sup>2</sup>	-0,66
<i>P. mirabilis</i> (ATCC® 7002)	2-6 °C	4,33 x 10 <sup>2</sup>	3,76 x 10 <sup>2</sup>	3,23 x 10 <sup>2</sup>	-0,13
	20-24 °C	4,33 x 10 <sup>2</sup>	2,96 x 10 <sup>2</sup>	1,47 x 10 <sup>2</sup>	-0,47
<i>S. saprophyticus</i> (ATCC® 15305)	2-6 °C	9,67 x 10 <sup>2</sup>	6,11 x 10 <sup>2</sup>	5,02 x 10 <sup>2</sup>	-0,28
	20-24 °C	9,67 x 10 <sup>2</sup>	5,54 x 10 <sup>2</sup>	5,11 x 10 <sup>2</sup>	-0,28
<b>Recovery of Additional Relevant Pathogenic Organisms of the Urinary Tract in UriSponge™</b>					
Organism	Holding Temperature	T=0	T=24	T=48	T=48 hours Log reduction (-) or Log increase (+)
<b>Average CFU recovered N=9 (from three lots)</b>					
<i>C. freundii</i> (ATCC® 8090)	2-6 °C	2,36 x 10 <sup>3</sup>	2,06 x 10 <sup>3</sup>	1,76 x 10 <sup>3</sup>	- 0,13
	20-24 °C	2,36 x 10 <sup>3</sup>	1,75 x 10 <sup>3</sup>	1,55 x 10 <sup>3</sup>	-0,19
<i>C. glabrata</i> (ATCC® MYA-2950)	2-6 °C	1,52 x 10 <sup>3</sup>	7,78 x 10 <sup>2</sup>	6,21 x 10 <sup>2</sup>	-0,39
	20-24 °C	1,52 x 10 <sup>3</sup>	5,38 x 10 <sup>2</sup>	3,23 x 10 <sup>2</sup>	-0,67
<i>E. cloacae</i> (ATCC® 13047)	2-6 °C	1,01 x 10 <sup>3</sup>	8,53 x 10 <sup>2</sup>	6,71 x 10 <sup>2</sup>	-0,29
	20-24 °C	1,01 x 10 <sup>3</sup>	6,83 x 10 <sup>2</sup>	1,40 x 10 <sup>3</sup>	0,15
<i>M. morgani</i> (ATCC® 25829)	2-6 °C	2,27 x 10 <sup>3</sup>	2,19 x 10 <sup>3</sup>	1,38 x 10 <sup>3</sup>	-0,22
	20-24 °C	2,27 x 10 <sup>3</sup>	1,61 x 10 <sup>3</sup>	1,40 x 10 <sup>3</sup>	-0,21
<i>S. agalactiae</i> (ATCC® 12386)	2-6 °C	2,26 x 10 <sup>3</sup>	1,85 x 10 <sup>3</sup>	1,23 x 10 <sup>3</sup>	-0,29
	20-24 °C	2,26 x 10 <sup>3</sup>	1,15 x 10 <sup>3</sup>	8,39 x 10 <sup>2</sup>	-0,45



#### Microorganism release study (centrifugation and manual release methods)

The ability of UriSponge™ to release organisms suspended in filtered synthetic urine at known concentrations using centrifugation and manual method was compared with the concentration of the organisms in the initial spiked synthetic urine. See Table 3.

Table 3. Performance of UriSponge™ in releasing a select set of uropathogenic microorganisms using the centrifuge and manual release methods

Organism	Average CFU/mL Recovered: Spiked Urine	Average CFU/mL Recovered: Time 0 hrs Centrifugation Release	Average CFU/mL Recovered: Time 0 hrs Manual Release	Centrifugation Release vs. Spiked Urine Log reduction (-) or increase (+)	Manual Release vs. Spiked Urine Log reduction (-) or increase (+)
<i>C. albicans</i> (ATCC® 24433)	$6.17 \times 10^2$	$5.38 \times 10^2$	$5.47 \times 10^2$	-0.06	-0.05
<i>E. coli</i> (ATCC® 25922)	$1.39 \times 10^3$	$1.49 \times 10^3$	$1.46 \times 10^3$	0.03	0.02
<i>S. saprophyticus</i> (ATCC® 15305)	$1.19 \times 10^3$	$1.19 \times 10^{3*}$	$1.22 \times 10^3$	-0.002	0.01

\*CFU/mL for this sample was  $1.186 \times 10^3$  before rounding to two decimal places.

#### Fill volume study

The ability of UriSponge™ to maintain the viability of organisms was evaluated in case of non-saturated sponges, verifying the lack of toxicity effect on the urine flora. See Table 4.

Table 4. Results of UriSponge™ fill volume study

Organism	Average CFU/mL Recovered: Time 0 hrs	Average CFU/mL Recovered: Time 48 hrs at 2-6 °C	T = 48 hours Log reduction (-) or increase (+)
<i>E. coli</i> (ATCC® 25922)	$1.73 \times 10^4$	$2.67 \times 10^3$	-0.81
	$1.90 \times 10^4$	$3.63 \times 10^3$	-0.72
	$2.17 \times 10^4$	$2.35 \times 10^3$	-0.97
<i>P. aeruginosa</i> (ATCC® 27853)	$1.22 \times 10^4$	$1.69 \times 10^3$	-0.86
	$9.70 \times 10^3$	$1.35 \times 10^3$	-0.86
	$1.02 \times 10^4$	$1.33 \times 10^3$	-0.89
<i>P. mirabilis</i> (ATCC® 7002)	$1.96 \times 10^4$	$2.97 \times 10^3$	-0.82
	$2.13 \times 10^4$	$2.48 \times 10^3$	-0.93
	$1.50 \times 10^4$	$2.80 \times 10^3$	-0.73

## REFERENCES

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## INDEX OF SYMBOLS

Symbol	Meaning
	Manufacturer
	In vitro diagnostic device
<b>Rx Only</b>	For professional use
	Do not re-use
	Catalogue number
	Sterilized using irradiation
	Temperature limits
	Use-by date
	Consult instructions for use
	Batch code (lot)
	Contents sufficient for <n> tests



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