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CITOTEST®
Technical Data Sheet

Second edition
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CITOSWAB™ Series

1. ProductRanges

Type	P/N
Collection swabs	2122-0001, 2122-0002, 2122-0004, 2122-0005, 2122-0006, 2122-0007, 2122-0008, 2122-0009, 2122-0010, 2122-0011, 2122-0012, 2122-0013, 2122-0014, 2122-0015, 2122-0016, 2122-0017, 2122-0018, 2122-0019, 2122-0020, 2122-0021, 2122-0022, 2122-0261, 2122-0262, 2122-0263, 2122-0201, 2122-0202, 2122-0231, 2122-0232
Transport swabs	2120-0001, 2120-0002, 2120-0003, 2120-0004, 2120-0005, 2120-0006, 2120-0007, 2120-0008, 2120-0009, 2120-0010, 2120-0011, 2120-0012, 2120-0013, 2120-0014, 2120-0015, 2120-0016, 2120-0017, 2120-0018, 2120-0019, 2120-0020, 2120-0021, 2120-0022, 2120-0023, 2120-0024, 2120-0025 , 2120-1203, 2120-1101,2120-1103, 2120-0521, 2120-0621, 2120-0503, 2120-0603

2. International Standards

Comply with Quality Control of Microbiological Transport Systems; Approved Standard. CLSI document M40-A [ISBN 1-56238520-8].

3. Intended Use

CITOSWAB™ SERIES is a sterile ready-to-use system, intended for biological sampling when a test is to be performed immediately, or does not need to keep the organisms viable, e.g. direct smear examination, as well inoculation by Roll-plate method, such as susceptibility testing by Kirby-Bauer or E-test.

4. Summary and Principle

Microbiologically, reliable sampling and safe transporting of a clinical specimen are key procedures to get perfect diagnosis of infectious diseases. This can be accomplished using the CITOSWAB™ SERIES. CITOSWAB™ SERIES is composed with a sample swab, or a sample swab supplied ina transport tube. The swab tip is non-toxic and allows best specimen absorb and release, particularly for microorganisms. Straight and flexible shafts are suitable for multiple body site sampling.

CITOSWAB® series is provided with a complete range of sticks and tips including cotton swabs, viscose swabs and polyester swabs. All of them are in compliance with European Medical Device Directive 93/42/EEC, and validated as a Class I (collection swabs)，Class Is（Sterile swab） and Class IIa (Transport swabs) medical device.

5. Appearance Descriptions

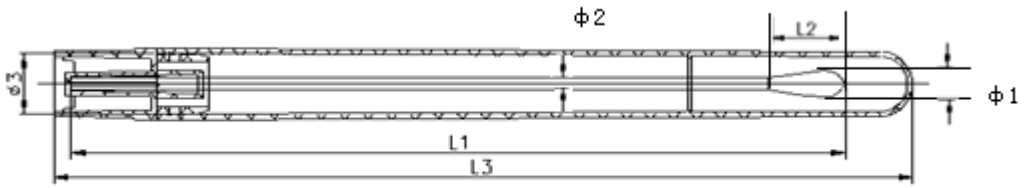
General appearance and dimensions

Type A: Collection swabs (a swab packed in pouch)



	PP/PS stick		Viscose tip	
	L1	φ2	L2	φ1
Dimension, mm	150±3	2.5±0.2	16±3	5±0.5

Type B: Transport swabs (a swab packed in tube)



Transport swab

Type (Dimension, mm)	Stick		Tip		Tube & cap	
	L1	φ2	L2	φ1	L3	Φ3
PP/PS stick+ Viscose tip	150±3	2.5±0.2	16±3	5±0.5	165±2	11±0.1
Al/SS stick+ Viscose tip	150±3	0.9-1.0	12±2	2.5±0.2	165±2	11±0.1

6. Package Information

Package types	WRAPPAGE	DIMENSION	Qty/Pk
PACK 1	Individual peel or flow pack	180×19.5×4 mm (Type A)	Individual
		204×39×11 mm (Type B)	Individual
PACK 2	Dispenser box	260×160×210 mm(Type A)	500pcs/dispener box
		260×160×175 mm(Type B)	250sets/ dispener box
PACK 3	Double wall corrugated cardboard carton	660×270×230 mm(Type A)	4×500pcs/dispener box
		660×270×190 mm(Type B)	4×250sets/ carton

7. Sterilization

☑ STERILE EO ☑ STERILE R ☐ STERILE A ☑ Non-sterile

8. Precautions

- For laboratory and *in vitro* diagnostic use only.
- Observe approved biohazard precautions and aseptic techniques. To be used by adequately trained and qualified personnel.
- Sterilize all biohazard waste before disposal.

- Directions for use must be followed carefully.
- Do not re-sterilize unused swabs and re-pack.
- Not suitable for any other application than intended use.

9. Storage and Shelf Life

CITOSWAB™ series must be stored in room temperature (2-30℃). The expiration date is 36 month for the product in its intact packaging when stored as directed. The product should not be used if there isa breakage of the pouch, or if the expiration date has passed.

10. Materials supplied

Each CITOSWAB™ seriesunit consists of a sterile package containing a sample swab which has a tip winded with soft viscose fiber, or a sample swab supplied in a pre-labeled plastic tube.

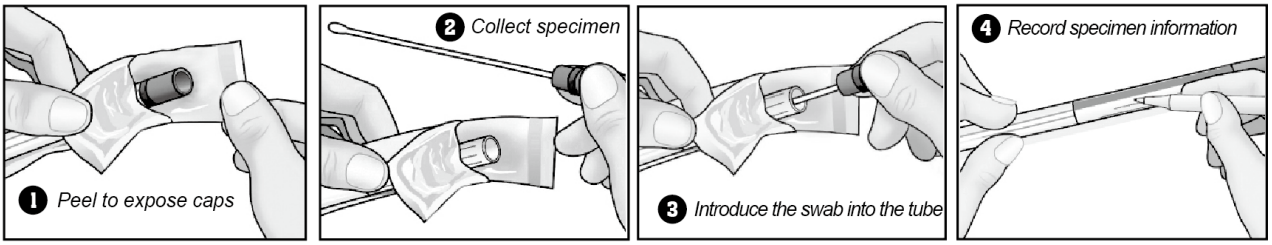
11. Materials required but not supplied

Appropriate materials for isolating and culturing aerobes, anaerobes and fastidious bacteria, include culture plates, incubation systems and so on.

12. Instructions for use

The simple directions in diagrams are printed on each CITOSWAB™ SERIES unit, see Figure1.

1. Open the sterile pouch to expose caps.
2. Just hold the swab by the attached cap to collect specimen with the sterile swab tip.
3. Insert the swab into the tube and seal with its attached cap tightly.
4. Record the required information on the label of the transfer tube and send to the laboratory with minimum delay.



Important notice: ***PLEASE CAREFULLY CHECK THE CAP COLORS FOR YOUR CONSIDERED USES.***

Figure 1 The simple directions in diagrams

Limitations

- The condition of the specimen received by the laboratory for culture is a significant variable in recovery and final identification of the suspect pathogen. An unsatisfactory specimen (unsatisfied specimen collection from patients, overgrown by contaminants, containing nonviable organisms, or having the number of pathogens greatly diminished) can lead to erroneous or inconclusive results.
- Clinical specimens should be inoculated to an appropriate culture medium upon receipt in the laboratory. After inoculation, specimens should be placed immediately into appropriate atmosphere to ensure optimal growth of bacteria.

13. Quality control

All batches of CITOSWAB™ series are tested for general characteristics, sterility and non-toxic to bacteria.

14. References

1.Perry J L, Ballou D R, and Salyer J L. Inhibitory properties of a swab transport device. Clin Microbiol, 1997, 35: 3367-3368.

2. Sng E-H, Rajan VS, Teo K-L, Goh A-J. The recovery of *Neisseria gonorrhoeae* from clinical specimens: effects of different temperatures, transport times, and media. Sex Trans Dis. 1982, 9: 74-78.

3. CLSI. Quality Control of Microbiological Transport Systems; Approved Standard. CLSI document M40-A [ISBN 1-56238520-8]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania19087-1898USA.

15. Version Information

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