

# TECHNICAL DATA SHEET

## Enrichment media LIM Broth with flocked swab

code 304213KF

code	ml	description	break point	presentation	case quantity	case weight (kg)	case volume (m <sup>3</sup> )	pallet quantity
304213KF	2	13 x 82 mm skirted tube with standard flocked swab	80 mm	flow-pack	6x60	4.00	0.056	32

Tube: Directive 98/79/CE. "In vitro" diagnostic medical devices

Swab: Directive 93/42/CEE. Medical device

### INTENDED USE - DESCRIPTION

Selective enrichment medium for Group B Streptococcus, including *S. agalactiae*. The kit consists of a skirted tube with conical bottom and screw cap, containing 2 ml of LIM broth, and a standard flocked swab. Packed in flow pack with the basic information and instructions printed.

The flocked swab has a break point at 80mm for easy insertion into the tube and subsequent transport.

Using standard flocked swabs, allows taking vaginal, rectal, or vaginal-rectal specimens to identify the possible presence of Group B streptococci in pregnant women. Once the sample is taken, keep the swab in the transport medium and preferably store it at low temperature until it can be processed in the laboratory.

### INSTRUCTIONS

1. Open the flow-pack using both hands pulling opposite sides.
2. Agitate the tube smoothly.
3. Open the peel-pack and retrieve the swab for the sample collection.
4. Open the tube with the other hand and place the swab inside so that it is covered with the media.
5. Align the breakpoint of the swab with the top of the tube lightly pressing the swab downwards. Break the swab by the breakpoint by supporting it on the inner edge of the tube.
6. Discard the leftover piece of stick, screw cap tightly and shake the sample to elute it into the medium.
7. Identify the patient on the tube label and send to the laboratory for analysis


 Swab:  0318

 Tube:  

### SAMPLE PROCESSING

- Incubate aerobically or in a CO<sub>2</sub> rich atmosphere at 35-37 ° C for 18-24 hours.
- After incubation, if turbidity is observed in the tube, proceed to inoculation on a plate with a suitable medium (Blood or Grenade agar); Lengthen the incubation for a further 24 hours before confirming positive results.
- Plate inoculation can be done:
  - By inoculation and automatic seeding
  - By direct inoculation of the swab
 Inoculate 100 µl of the suspension with a micropipette and subsequent seeding with a loop.
- Incubate the plates for 18-24 hours or, if necessary, up to 48 hours at 35-37 ° C under aerobic conditions.
- Observe for growth by the presence of gray or non-hemolytic beta-hemolytic colonies (group B streptococci (GBS) are gram positive cocci, negative catalysis). If Group B streptococci colonies are not observed at the end of the 18-24 hours, prolong the incubation up to 48 hours.
- For the detection of group B streptococcal antigens, agglutination or colony isolation tests can be performed.

WRITTEN	VERIFIED	AUTHORISED
Joan Ibáñez Marketing Department	Anna Mir Technical, Development, Quality and Environment Director	Mónica Torras Sales and Marketing Director

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### COMPONENTS

The kit includes:

- Tube with transport medium
- Flocked swab
- Flow pack package

Swab: sterile by radiation (R).

Labeled with identification, batch number and expiry date.

Do not expose to the sun continuously. Keep between 2 °C and 30 °C

Shelf life **16 months** from manufacture.

### ADVANTAGES OF DELTASWAB SYSTEM

- Compatible with the new inoculation automation and sample streaking equipment.
- Compatible with molecular diagnostic techniques.
- Greater feasibility of the sample as it is totally suspended in the medium.
- Allows different homogeneous inocula to be obtained from the same sample.
- Adaptable to any working protocol.
- Minimises any possible cross-contamination: less handling and maximum tightness.
- More comfort for the user: conical base which facilitates stirring and higher stability of the tube with skirt base.
- Standardises the receipt of samples at the microbiology labs.
- Facilitates manual streaking.
- Allows direct extension on the glass slide as the medium does not contain agar.

### FEATURES AND ADVANTAGES OF FLOCKED SWABS

- Support made of polystyrene --> Optimum safety.
- Head swab made of flocked fibers --> increased absorption and elution of the sample on the media.
- Maximum adaptability: wide range
- Maximum comfort: anatomical and ergonomic design.

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### IN COMPLIANCE WITH

Directive 98/79/CE. "In vitro" diagnostic medical devices.

Directive 93/42/CEE. Medical Devices (swab)

Standards related with the Quality System o with the product:

- UNE EN ISO 9001 Quality Management System
- UNE EN ISO 13485 Medical Devices - Quality Management Systems
- UNE EN ISO 14971 Risk Management of Medical Devices
- UNE EN ISO 15223-1 Medical devices. Symbols used on labels, labeling and information to be supplied. Part 1: General requirements.

### LABEL DESIGN



The label design is a rectangular box with a dark blue header and a white body. The header contains the 'dswab' logo in white and 'LIM BROTH' in white text. The body contains three lines of text: 'Name', 'Hospital', and 'Date' followed by 'Time'. Below the text are three horizontal lines for input. At the bottom of the label, there are several icons and text: a CE mark, an IVD mark, a crossed-out X mark, a book icon, a temperature icon showing 2°C and 30°C, a factory icon, and the text 'TEC 1436/0 DELTALAB S.L. Plaza Verneda, 1 08191 Rubí - Barcelona (SPAIN)'.

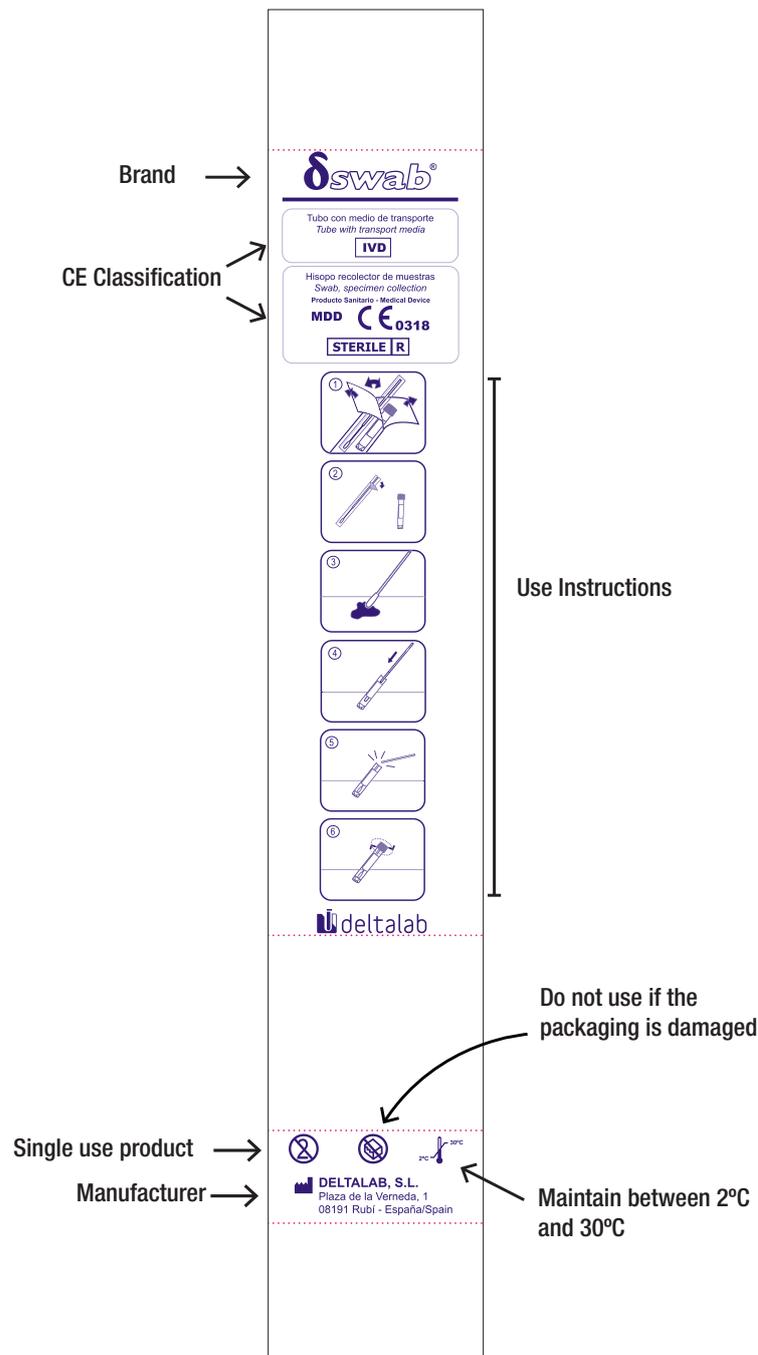
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#### FLOW-PACK



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