

SIGMA GBS™ BROTH MEDIUM

CODE	DESCRIPTION	SPECIMEN/SAMPLE SITE
MWGBS	Σ-GBS™, 2ml Liquid Sigma GBS medium, standard plastic shaft Sigma swab, light blue colour coded cap	Vagina & Rectum
MWGBST	Σ-GBS™, 2ml Liquid Sigma GBS medium only, light blue colour coded cap (Tube only)	Clinical

MDD: European Medical Devices Directive 93/42/EEC

IVD: European In Vitro Diagnostic Medical Devices 98/79/EC

***For Tube Only IVD's, the Notified Body number for CE, and Approved Body number for UKCA do not appear on the markings.**

INTENDED USE

Sigma GBS™ Specimen Collection & Culture Device System is intended to preserve the viability and infectivity of *Streptococcus agalactiae* in specimens after collection and during transport from the collection site to the testing laboratory, and upon incubation at 37°C promote selective enrichment of the *Streptococcus agalactiae* bacteria. Following incubation Σ-GBS™ specimens are processed using standard clinical laboratory operating procedures for the culture of *Streptococcus agalactiae*.

The device is primarily intended for use in the screening of pregnant women to identify those who may be colonised with *Streptococcus agalactiae* which presents a significant risk of neonatal infection resulting in severe illness or even death. Sigma swabs® with foam buds are used to sample from the vagina and rectum, then placed in the tube of medium for transport and processing.

SUMMARY AND PRINCIPLES

One of the routine procedures in the diagnosis of infections involves the collection and transportation of a clinical swab specimen from the patient to the laboratory. Specimens containing live microorganisms may be submitted to a laboratory for diagnosis or confirmation of the patient's illness.

REAGENTS

Σ-GBS™ includes a tube of Liquid GBS Medium

Peptone

Dextrose

Sodium chloride

Disodium phosphate

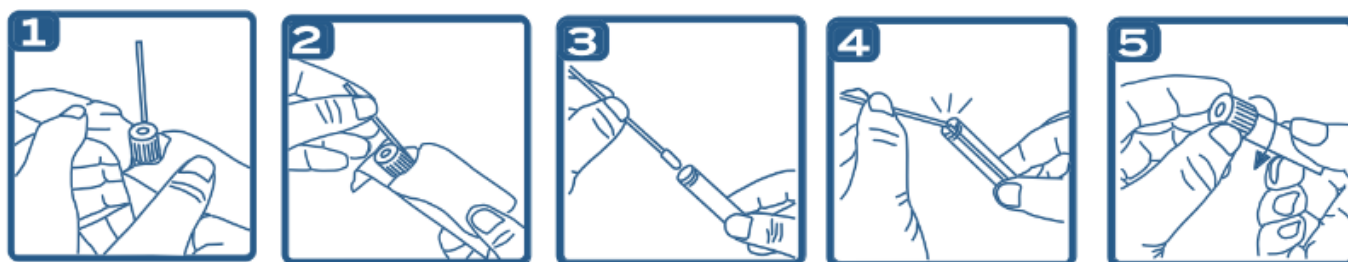
Sodium carbonate

Yeast extract

Colistin

Naladixic acid

INSTRUCTIONS FOR USE plus picture



Specimen collection is a critical step in the isolation and accurate identification of aetiological agents of infectious disease. It is essential to follow correct procedures as described in recognised protocols and published reference manuals.

BROTH MEDIUM

1. Peel back pouch, remove vial and place on a flat surface. Loosen cap.
2. Withdraw one swab, and use to take specimen from vaginal introitis or rectum. It is strongly recommended that separate swabs are used for each site. If a single swab is used, sample from vagina before rectum.
3. Remove cap from vial, insert swab into vial and snap off the non-bud end so that the remaining shaft fits within the vial. The shaft has a scored breakpoint to assist this process.
4. Replace cap, and turn until secure. The swab will become attached to the cap.
5. Fill in patient's details.
6. Transport to laboratory at ambient temperature (+5°C – 25°C), or under refrigerated conditions (+2°C- +8°C). Culture should be commenced as soon as possible.

PRECAUTIONS

For in vitro diagnostic use only

Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. Prior to discarding, swabs and other contaminated materials must be sterilized by autoclaving. Once a swab sample is collected it should be placed immediately into the transport tube where it comes into contact with transport medium. Swab specimens for microorganism isolation and/or detection should be submitted to the laboratory as quickly as possible after collection.

Care should be taken to avoid splashes and aerosols when snapping the swab shaft against the tube.

Do not use if package seal is broken.

Do not use if swab shaft is broken.

DO NOT FREEZE.

MATERIAL SAFETY INFORMATION

Σ-GBS™ plastic components do not contain latex or PVC.

STORAGE

Σ-GBS™ should be stored in a dry place at temperatures between + 5°C to 25°C.

DO NOT FREEZE

EXPIRY DATE

9 months from date of manufacture, expiration date is shown on the tube label, peel pouch, and box label.

SPECIMEN COLLECTION AND HANDLING

Materials Provide

Swab for collection of specimen*

Transport tube with Liquid GBS medium.

***There is no swab with MWGBST**

Materials required but not provided:

External transport container compliant with local regulations

Microbiology facilities for processing specimens

Including equipment and consumables for culture or molecular processing

PROCESSING SPECIMENS

Σ-GBS™ tubes contain Liquid GBS Broth medium (similar to Todd Hewitt and Lim Broths) to keep the specimen moist, and to maintain any Streptococcus microorganisms in a viable condition until they can be investigated at the laboratory. Following transport, incubation of the tube at 37°C promotes the growth of Streptococcus bacteria while inhibiting commensal bacteria such as *Escherichia coli*. The enriched Streptococcus can then be identified by standard techniques such as culture.

Σ-GBS™ is supplied with a standard Sigma Swab® (MWGBS) with bud suitable for most sampling vagina and/or rectum. The bud materials are not coated in protein or any other substances which could affect the specimen by providing nutrients leading to overgrowth of non-target commensal bacteria

QUALITY CONTROL

Each batch of Σ-GBS™ is tested for sterility, recovery of *Streptococcus agalactiae*, and inhibition of *Escherichia coli*.

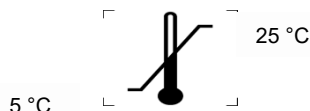
LIMITATIONS

1. When collecting and processing specimens follow relevant safety guidance for the handling of potentially infectious material, and, for the maintenance of the biological integrity of the specimen.
2. The condition, time of collection, and volume of specimen are all significant factors in obtaining accurate and reliable results, whether using culture or molecular techniques. Always follow the recommended guidelines for specimen collection.

RECOVERY STUDIES

- This product is for Single Use Only. Attempted reuse may cause a serious risk of infection and inaccurate results.
- Do not resterilise unused swabs
- Do not repack components
- Not suitable for other uses other than the stated intended use.
- The use of this product with any rapid diagnostic kit or with diagnostic instrumentation should be validated by the user.
- Do not use this product if the swab is visibly damaged
- Do not use excessive force or pressure when collecting swab samples as this may cause the swab shaft to break
- Σ-GBS™ it is Class Is Medical Devices in accordance with the European Medical Devices Directive 93/42/EEC and as such can be used for sampling all body surfaces and orifices.
- Medium is not to be taken
- Follow directions for use. The manufacturer cannot be held responsible for unauthorized or unqualified use of the product.
- Specimen collection and processing should only be conducted by or under supervision of trained personnel.
- All specimens are to be considered infectious, and must be handled with appropriate precautions, and disposed of as clinical infectious waste.
- Σ-GBS™ Medium is not to be used for premoistening the swab prior to specimen collection, or for premoistening in any way the sampling site.

REGULATORY SYMBOLS APPLICABLE FOR FAMILY GROUP



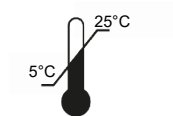
Advena Ltd, Tower Business Centre, 2nd Fl.,
Tower Street, Swatar, BKR 4013, Malta



Swiss AR Services AG Industriestrasse 47
CH-6300 / Zug

SYMBOLS & DEFINITIONS





Temperature Limitation



Do Not Reuse



Do Not Use If Package Damaged



Manufacturer



1639

CE Mark



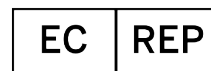
In Vitro Diagnostic Medical Device



Medical Device



Method of Sterilisation Using Irradiation



Authorised Representative in the European Community



SGS Approval Mark



Use By (YYYY/MM)



Date of Manufacture



UKCA Mark



Catalogue Number



Batch Code



Consult Instructions for Use



Peel Here



Contains Sufficient for <n> Tests



Swiss Representative

