

LBC MEDIUM
ANVISA #80429030010
Presentation

Conical bottom plastic tube with screw cap and leak-proof rings containing 3ml or 5ml.

Plastic flask with flat bottom and base and screw cap with 10ml, 18ml or 20ml.

Tubes can be combined with a cervical brush, an Ayre spatula and/or a M-size speculum in a kit.

Sterilization method

Aseptic filtration method.

Application

The LBC medium is intended for use in the collection, transportation, and preservation of cervical cells for cytology tests in liquid-based and/or molecular biology tests.

Principle

Methanol-free ready-to-use solution developed to preserve collected material for liquid-based cytology and molecular diagnosis of sexually transmitted infections.

How to use

- Using the plastic spatula, collect the sample from the ectocervix and the vaginal cul-de-sac.
- Immediately insert the spatula into the LBC solution and shake vigorously to release the collected cells. Discard the spatula after use.
- Using the cervical brush, collect the endocervix sample by inserting the brush into the endocervical canal until only the last bristles are visible and slowly rotate half-turn in one direction only.
- Immediately insert the cervical brush into the LBC solution, shake vigorously, and rub the bristles against the wall of the vial promoting the release of the collected cells. Discard the brush after use.
- Close the plastic tube tightly to prevent leakage.
- Fill in the vial label with the patient's data.

Quality Control

Test	Result
Appearance	Liquid medium, colorless, clear, may contain slight precipitate
pH at 25°C	7.3 ± 0.2

Results interpretation

Detection of the target genetic material and cytology analyses should be in accordance with official compendia or internal laboratory methodology.

Precautions and special care

Do not use lubricants for collection. Before collection, remove any excess mucus, inflammatory exudate, or other discharge present. The cervix should not be cleaned with saline wash. If colposcopy is planned, collect the sample before applying acetic acid or iodine. The presence of blood or abnormal vaginal content may interfere with the results. The patient should not use vaginal medication, vaginal contraceptives, or vaginal douches within 48 hours prior to collection. Sexual abstinence is required within 72 hours prior to collection. The patient should not be menstruating.

Keep away from fire, heat, and sparks. Product intended for *in vitro* diagnostic use only.

Restricted for use by professionals. Do not inhale or ingest.

Do not use the product beyond the expiration date, with signs of contamination, or if it has changed color. In the presence of contamination, the product should be immediately discarded.

Do not use the product if the packaging is damaged or tampered with.

Storage

Store between 15-35°C in a dry place and protect from light. No refrigeration is required.

Shelf-life

1 year from the date of manufacture.

Disposal of the product

After use, the product must be handled at the generating unit before environmentally appropriate final disposal, in accordance with official regulations.

Quality Guarantee

bioBoaVista guarantees the quality of its products as long as they are used according to their respective instructions and in accordance with national and international references. bioBoaVista does not take responsibility for the use of its products for purposes other than those described and approved by the company. All clinical diagnoses should be analyzed in conjunction with clinical evidence and not solely based on laboratory results.