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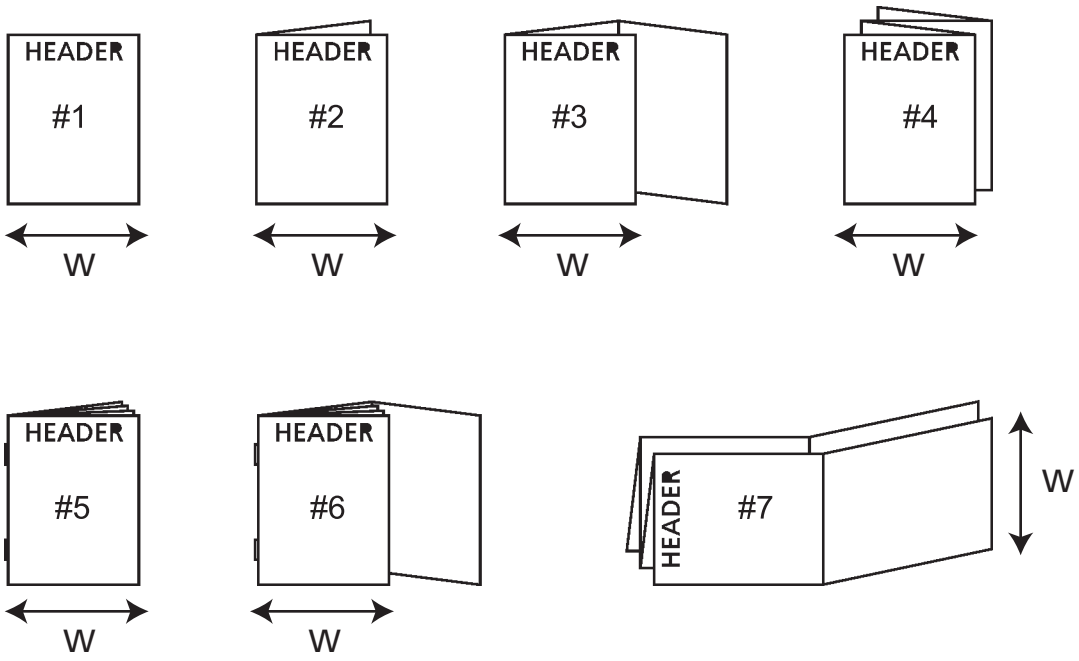


8. See specification control no. N/A for material information.
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# BD BBL Lowenstein-Jensen Medium + PACT

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## INTENDED USE

**BBL** Lowenstein-Jensen Medium + PACT is intended for the cultivation of *Mycobacterium tuberculosis* and other mycobacterial species.

## SUMMARY AND EXPLANATION

**BBL** Lowenstein-Jensen Medium + PACT is an egg-based medium containing antimicrobials. The DIN standard 58943-3 "Diagnosis of tuberculosis – Part 3: Detection of mycobacteria by culture methods" recommends the use of an egg-based medium supplemented with antimicrobials; e.g., polymyxin B 200,000 units/L, amphotericin B 10 mg/L, carbenicillin 50 mg/L and trimethoprim 10 mg/L (PACT) for the egg-based culture media.[1]

Lowenstein originally formulated a medium for cultivation of mycobacteria in which congo red and malachite green were incorporated for the partial inhibition of other bacteria.[2,3] These dyes were similarly used by other investigators, notably Sonnenschein[4] and Hohn[5]. In the United States the gentian violet media of Corper[6] and Petroff[7] were popular, along with the medium of Petragnani, which contained malachite green. The present formula, developed by Jensen[8], has a slightly different citrate and phosphate content, does not contain congo red, and has an increased malachite green concentration.

In 1972, Mitchison et. al. developed a selective medium for mycobacteria by adding polymyxin B, amphotericin B, carbenicillin and trimethoprim lactate to Middlebrook and Cohn 7H10 Agar.[9] **BBL** Lowenstein-Jensen Medium + PACT uses the same combination of selective agents.

## PRINCIPLES OF THE PROCEDURE

Lowenstein-Jensen Medium Base is a relatively simple formulation that requires supplementation in order to support the growth of mycobacteria. Glycerol and egg mixture are added prior to the inspissation process. These substances provide fatty acids and protein required for the metabolism of mycobacteria. The coagulation of the egg albumin during sterilization provides a solid medium for inoculation purposes. Asparagine is added to promote the initiation of growth and increase the growth rate. Partial inhibition of bacteria is achieved by the presence of the malachite green dye.

The selective nature of **BBL** Lowenstein-Jensen Medium + PACT is due to the incorporation of polymyxin B, amphotericin B, carbenicillin, and trimethoprim lactate in its formula. Carbenicillin is a synthetic penicillin, which has a bactericidal effect on gram-negative bacteria, especially *Pseudomonas aeruginosa* and *Proteus* sp., by inhibiting cell wall synthesis.[10] Polymyxin B is a polypeptide antibiotic that is inhibitory for gram-negative bacteria due to its damaging of their plasma membranes, which affects the permeability of the cells.[10] Amphotericin B is a heptaene antibiotic, which is active in the inhibition of fungi by altering the permeability of cell membranes, which contain cholesterol or ergosterol, thereby allowing permeation of various micromolecular compounds into the cell.[11] Trimethoprim inhibits folic acid synthesis in gram-positive bacteria that require folic acid.[12]

## REAGENTS

### BBL Lowenstein-Jensen Medium + PACT

Approximate Formula* per Liter Medium

| | | |
|---|---|---|
| Potato Starch | 18.60 | g |
| L-Asparagine | 2.23 | g |
| Potassium Phosphate Monobasic | 1.55 | g |
| Sodium Citrate | 0.37 | g |
| Malachite Green | 0.25 | g |
| Magnesium Sulfate | 0.15 | g |
| Glycerol | 7.44 | mL |
| Whole Eggs | 620.00 | mL |
| Purified Water | 373.00 | mL |
| Polymyxin B | 200,000.00 | I.U. |
| Amphotericin B | 10.00 | mg |
| Carbenicillin | 100.00 | mg |
| Trimethoprim | 10.00 | mg |

*Adjusted and/or supplemented as required to meet performance criteria.

### Warnings and Precautions

For *in vitro* Diagnostic Use.

Tubes with tight caps should be opened carefully to avoid injury due to breakage of glass.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[13-16] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids. Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving.

Biosafety Level 2 practices and procedures, containment equipment and facilities are required for non-aerosol-producing manipulations of clinical specimens such as preparation of acid-fast smears. All aerosol-generating activities must be conducted in a Class I or II biological safety cabinet. Biosafety Level 3 practices, containment equipment and facilities are required for laboratory activities in the propagation and manipulation of cultures of *M. tuberculosis* and *M. bovis*. Animal studies also require special procedures.[15]

**Storage Instructions**

On receipt, store tubes in the dark at 2–8 °C. Avoid freezing and overheating. Do not open until ready to use. Tubed media stored as labeled until just prior to use may be inoculated up to the expiration date and incubated for the recommended incubation times. Minimize exposure to light.

**Product Deterioration**

Do not use tubes if they show evidence of microbial contamination, discoloration, drying or other signs of deterioration.

## SPECIMEN COLLECTION AND HANDLING

Specimens suitable for culture may be handled using various techniques. For detailed information, consult appropriate texts.[17,18] Specimens should be obtained before antimicrobial agents have been administered. Provision must be made for prompt delivery to the laboratory.

## PROCEDURE

**Material Provided:** Lowenstein-Jensen Medium + PACT

**Materials Required But Not Provided:** Ancillary culture media, reagents, quality control organisms and laboratory equipment as required for this procedure.

**Test Procedure:** Observe aseptic techniques.

The test procedures are those recommended by the Centers for Disease Control and Prevention (CDC) for primary isolation from specimens containing mycobacteria.[19] N-acetyl-L-cysteine-sodium hydroxide (NALC-NaOH) solution is recommended as a gentle but effective digesting and decontaminating agent. For detailed decontamination and culturing instructions, consult an appropriate reference.[18-21]

Following inoculation, keep test containers shielded from light and place in a suitable system providing an aerobic atmosphere enriched with 5 to 10% carbon dioxide. Incubate at 35 ± 2 °C.

Media should be incubated in a horizontal plane until the inoculum is absorbed. Tubes should have screw caps loose for the first 3 weeks to permit the circulation of carbon dioxide for the initiation of growth. Thereafter, to prevent dehydration, tighten caps; loosen briefly once a week. Stand tubes upright if space is a problem.

**NOTE:** Cultures from skin lesions suspected to be *M. marinum* or *M. ulcerans* should be incubated at 25 to 33 °C for primary isolation; cultures suspected to contain *M. avium* or *M. xenopi* exhibit optimum growth at 40 to 42 °C.[19] Incubate a duplicate culture at 35 to 37 °C.

## USER QUALITY CONTROL

1. Inoculate Lowenstein-Jensen Medium slants with stock cultures of the pertinent mycobacterial strains using sterile inoculating sticks.
2. Incubate tubes with loosened caps in an aerobic atmosphere supplemented with carbon dioxide at 35 ± 2 °C until heavy growth is obtained (usually within 2 to 3 weeks).
3. Harvest the growth with a sterile sharpened applicator stick by gently removing the cells from the surface of the medium with care being taken not to include culture medium with the cell crop.
   A. For *Mycobacterium tuberculosis* ATCC® 25177:
      1) Transfer growth to 5.0 mL Middlebrook 7H9 Broth with Glycerol in a sterile screw-capped glass tube containing sterile glass beads.
      2) Vortex well (several minutes) until suspension is free of large clumps.
      3) Compare this suspension to a McFarland #1 nephelometer standard. The suspension should be more turbid than the standard.
      4) Place the tube in a rack for 2 to 3 h at room temperature to allow large particles to settle to the bottom.
      5) Transfer the supernate to a sterile container.
      6) Adjust the turbidity of the suspension to the McFarland #1 standard by slowly adding sterile Middlebrook 7H9 Broth with Glycerol. Shake well.
      7) Dilute to $10^5$ CFU/mL before use. Mix well and streak-inoculate the test medium using a 0.01 mL calibrated loop.
   B. For all other mycobacterial strains:
      1) Transfer the growth to a sterile 50 mL screw-capped centrifuge tube containing 8 to 12 sterile glass beads (2 mm diameter) and 5 mL of Mycobacterium Diluent prepared as follows:
         a. Mix the following ingredients in a 1 L flask and adjust the pH, using 1N sodium hydroxide, to 6.7 to 7.0:

| | |
|---|---|
| Bovine Albumin (fatty acid free) | 1.0 g |
| Polysorbate 80 | 0.1 mL |
| Purified Water | 500.0 mL |

         b. Sterilize by membrane filtration (0.2 µ filter).
         c. Aseptically dispense in 5.5 mL amounts into sterile screw-capped tubes.

2) Emulsify the mycobacterial growth on the sidewall of a screw-capped centrifuge tube using an applicator stick. Mix the growth with the diluent.
3) Cap the tube and vortex approximately 10 min until the growth is well suspended and free of large clumps.
4) Add 15 mL of sterile Mycobacterium Diluent and mix thoroughly.
5) Compare this suspension to a McFarland #1 nephelometer standard. The suspension should be more turbid than the standard.
6) Place the tube in a rack for 2 to 3 h at room temperature to allow large particles to settle to the bottom.
7) Aspirate the supernate and transfer it to a sterile container. The suspension must be more turbid than a McFarland #1 standard and free of large particles. If large particles still are present, mix and allow to stand for an additional 1 h. Transfer the supernate to a sterile container.
8) Adjust the turbidity of the suspension to the McFarland #1 standard by slowly adding sterile Mycobacterium Diluent. Shake well.
9) Dispense aliquots of the suspension into freezer vials labeled to contain organism identification and date of preparation.
10) Freeze the suspensions by placing the vials in a low-temperature freezer at -60 °C. The vials can be stored for up to 6 months.
11) For use, remove the frozen vial from the freezer and quick-thaw the contents by placing the tube in a 30 to 35 °C water bath. Dilute to $10^5$ CFU/mL before use. Mix well and streak-inoculate the test medium using a 0.01 mL calibrated loop.

4. Incubate tubes with loosened caps at 35 ± 2 °C in an aerobic atmosphere supplemented with carbon dioxide.
5. Examine tubes after 7, 14, and 21 days for growth, selectivity and pigmentation.
6. Expected Results

| ORGANISM | RECOVERY |
|---|---|
| *Mycobacterium tuberculosis* H37Ra ATCC 25177 | Good |
| *Mycobacterium kansasii*, Group I ATCC 12478 | Good |
| *Mycobacterium fortuitum*, Group IV ATCC 6841 | Good |
| *Escherichia coli* ATCC 25922 | Partial to complete inhibition |

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

**RESULTS**

Cultures should be read within 5 to 7 days after inoculation and once a week thereafter for up to 8 weeks.

Record Observations:

1. Number of days required for colonies to become macroscopically visible. Rapid growers have mature colonies within 7 days; slow growers require more than 7 days for mature colony forms.
2. Pigment production

   White, cream or buff = Nonchromogenic (NC)

   Lemon, yellow, orange, red = Chromogenic (Ch)

   Stained smears may show acid-fast bacilli, which are reported only as "acid-fast bacilli" unless definitive tests are performed.

**LIMITATIONS OF THE PROCEDURE**

For identification, organisms must be in pure culture. Morphological, biochemical, and/or serological tests should be performed for final identification. Consult appropriate texts for detailed information and recommended procedures.[17, 18, 22]

**PERFORMANCE CHARACTERISTICS**

Prior to release, all lots of Lowenstein-Jensen Medium + PACT are tested for specific product characteristics. Using a 0.01 mL calibrated loop, samples are streak-inoculated with the following cultures diluted to contain $10^3$ colony-forming units (CFU) per 0.01 mL of *Mycobacterium kansasii* Group I (ATCC 12478), *M. fortuitum* Group IV (ATCC 6841) and *M. tuberculosis* (ATCC 25177); *Escherichia coli* (ATCC 25922) is diluted to contain $10^4$ CFU per 0.01 mL and inoculated in the same manner. After inoculation, the tubes are incubated with loosened caps at 35 ± 2 °C in an atmosphere supplemented with 5 to 10% carbon dioxide. Tubes are read for growth and pigmentation after 7, 14 and 21 days incubation. All mycobacteria exhibit moderate to heavy growth within 21 days. Colonial morphology is as follows: *M. kansasii* exhibits smooth cream-colored colonies when grown in the dark, becoming bright lemon yellow to orange when exposed to light; and *M. tuberculosis* and *M. fortuitum* are cream-colored (*M. fortuitum* may show greening due to dye absorption). *E. coli* shows no growth to fair growth after 14 days incubation.

**AVAILABILITY**

| Cat. No. | Description |
|---|---|
| 220502 | **BBL™** Lowenstein-Jensen Medium + PACT, Ctn. of 100 size A tubes |

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AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
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MMMM-MM-DD / MMMM-MM (MM = mėnesio pabaiga)
GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
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IVD

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LOT

Batch Code (Lot) / Код на партидата / Kód (číslo) šarže / Batch-kode (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (παρτίδα) / Código de lote (lote) / Partii kood / Numéro de lot / Lot (kod) / Tétel száma (Lot) / Codice batch (lotto) / Топтама коды / 배치 코드(로트) / Partijos numeris (LOT) / Partijas kods (laidiens) / Lot nummer / Batch-kode (parti) / Kod partii (seria) / Código do lote / Cod de serie (Lot) / Код партии (лот) / Kód série (šarža) / Kod serije / Partinummer (Lot) / Parti Kodu (Lot) / Код партії / 批号（亚批）

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