# Art. 114.0100

## TSA + LTG + β-Lac 2G Contact CSG

| | Technical Data |
|---|---|
| **Use in** | • Pharmaceutical Industry in clean rooms and isolators<br>• For industrial, laboratory & research applications only |
| **Use for** | • Detection of aerobic and anaerobic micro-organism<br>• Contact sampling, personnel monitoring, as well as active air monitoring<br>• Isolation and growth of fastidious bacteria, yeasts and molds<br>• Especially designed for use in environments with exposure to penicillins, cephalosporins and carbapenems<br>• β-Lactamase 2G is a broad spectrum ß-lactamase which can inactivate penicillins, most of the 1st, 2nd,3rd, 4th and 5th generation cephalosporins as well as carbapenems<br><br>The medium should be applied with a uniform and steady pressure to the surface for few seconds. After sampling the surface must be cleaned to remove residues of the medium. |
| **Typical composition per liter** | Basic medium according to Ph. Eur. 2.6.12, 2.6.13 and USP <61>, <62><br><br>Casein peptone 15 g; Soy peptone 5 g; NaCl 5 g; Agar 15 g; Lecithin (L) 0.7 g; Polysorbate 80 (T) 5 g; Glycine 2 g; β-Lactamase 2G<br><br>This medium can be adjusted / or supplemented according to the performance criteria required. |
| **Irradiation** | • Irradiated at 9 – 20 kGy |
| **Filling volume** | • 16 – 19 mL |
| **Packaging** | • Triple bagged, staples of 10 plates<br>• Transparent<br>• High barrier foil for $H_2O_2$ as well as for water-vapor<br>• 10 staples of 10 plates per packaging unit<br>• Temperature isolated handle-bag in the cardboard-boxes |
| **Plates per box** | • 100 (10 staples with 10 plates each) |
| **Shelf life** | • 12 months from production date |
| **Storage conditions** | • Recommended storage temperature: 15 – 25 °C<br>• Should be stored at temperatures as stable as possible<br>• Avoid prolonged exposure to direct sunlight<br><br>• Before use: it is recommended to keep the plates upright (agar on the lower part, lid on the upper part) to avoid formation of extra condensation<br>• After use: it is recommended to keep the plates upside down (agar on the upper part, lid on the lower part) to reduce the risk of accumulation of condensation during incubation which can affect colony formation |

| | Technical Data |
|---|---|
| **Label** | • On the side, at the bottom part of the plate |
| **Label information** | • Product name: TSA+LTG+Lac2G<br>• Expiry date: YYYYMMMDD ➔ MMM in letters (e.g.: 2026Nov04)<br>• Lot-number<br>• Individual number<br>• Barcode |
| **Barcode** | • 2-dimensional (data matrix), 20 digits:<br>• Digits 1-3: Art.-No.<br>• Digits 4-9: Lot-Number<br>• Digits 10-14: Individual-Number<br>• Digits 15-20: Date (YYMMDD) |
| **Delivery** | • Temperature controlled delivery on request<br>• For shipments of larger amounts plastic pallets in Euro-size can be used |
| **Petri dish** | • Locking-lid plate, made from polystyrene<br>• Inner diameter: ~ 56.5 mm, thus providing an area of ~25 $cm^2$<br>• Outer diameter: ~ 66 mm<br>• Bottom part with 1 $cm^2$ square grid for facilitated evaluation<br>• Incubations in vent and closed position possible<br>• Specific design to improve binding of agar to plate<br>• Easy handling due to increased handling area<br>• The bottom of the Petri dish contains “condensation collection channels” which capture and retain potential condensation originating from the culture medium, thereby increasing sampling safety |
| **Lid positions** | • All plates are delivered in the non-locked position<br>• The plate contains two locked positions. If turning the lid clockwise the locked positions are in the following order:<br>1. Vent position<br>2. Closed position<br>• Please check the recommendations for use on page 5 |
| **Place of production** | PharmaMedia Dr. Müller GmbH<br>Gustav-Throm-Str. 1, 69181 Leimen - Germany |

## Quality control, Certificates

**Certificates**

Every batch of product can be obtained with a certificate of analysis (CoA):

| **Physico-chemical test parameters:** | | | | |
|---|---|---|---|---|
| Appearance | Slightly turbid, yellowish | | | |
| pH value | 7.1 – 7.5 | | | |
| Filling volume | 16 – 19 mL | | | |
| Irradiation | 9 – 20 kGy | | | |
| | | | | |
| **Growth Promotion test:** 10 – 100 CFU | | | | |
| *S. aureus* | ATCC 6538 | 30-35 °C | 1 day | 50-200% |
| *E. coli* | ATCC 8739 | 30-35 °C | 1 day | 50-200% |
| *P. paraeruginosa* | ATCC 9027 | 30-35 °C | 1 day | 50-200% |
| *B. spizizenii* | ATCC 6633 | 30-35 °C | 1 day | 50-200% |
| *C. albicans* | ATCC 10231 | 30-35 °C | 2-3 days | 50-200% |
| *A. brasiliensis* | ATCC 16404 | 30-35 °C | 2-3 days | 50-200% |
| | | | | |
| **Test for β-lactamase Plus activity:** 10,000 – 100,000 CFU | | | | |
| *S. aureus* | ATCC 6538 | 30-35 °C | 1 day | No inhibition |
| No inhibition by penicillin (10 IU), Meropenem (10 µg), Ertapenem (10 µg), Ceftriaxon (30 µg) and Cefazolin (30 µg) | | | | |
| | | | | |
| **Sterility control** | | | | No growth |

**Certificate of origin**

All media lots produced by PMM can be obtained with a Certificate of Origin (CoO). All animal derived raw materials are specified as follows:

- Raw material
- Tissue
- Animal source
- Country of origin
- Infectivity category (acc. to TSE guideline: EMA/410/01 current version)

**BSE policy**

In compliance with the current note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy via human or veterinary medicinal products, we check the CoO of raw material in respect to the specified animal source, the country of origin and the infectivity category. We neither store or process ruminant raw materials obtained from high infectivity tissues (IA) nor ruminant raw materials whose animal source originates from countries or regions with an undetermined risk (cat C/GBR IV).

**Temperature stress**

Art. 114.0100 has been exposed to temperature stress conditions (3 days at 2-8 °C as well as 3 days at 30-35 °C) and has passed shelf-life testing at least 30 days after the assigned expiry date. Shelf-life testing comprises all regular tests which are part of the normal release test of this article except for sterility control (see CoA).

## Quality control, Certificates

**Inactivation of ß-Lactam-antibiotics:**

**Test procedure**

Tests for inactivation of lactam antibiotics were performed on art. 214.0060, TSA+LTG+Lac 2G. The medium of art. 114.0100 and 214.0060 are identical in respect to media composition and enzyme added to the medium.

Test procedure: 100 µL of test suspension Mac Farland 0.5 were inoculated on a 90 mm **TSA+LTG-ß-Lactamase 2G** plate (art.-No. 214.0060). Test disks were applied on the plate directly after inoculation with the test strain. Tests were performed in double. Reference plate used was TSA+LTHT 90 mm CSG (art. 200.0060)

**Result:** see **table:** All tested disks with ß-lactam antibiotics except for ceftazidime were inactivated by PMM TSA+LTG+ß-lactamase 2G plate. As observed before, *E. coli* seems to be the most sensitive test strain, although due to the qualitative test procedure performed here only with ceftazidime a difference to the other test strain was observed.

Additional tests showed clearly better inactivation of ß-lactam antibiotics by the **TSA+LTG+β-Lactamase 2G** plates compared to older generation ß-lactamase plates (like TSA+LTG+β-lactamase +) with at least the following ß-lactam antibiotics:
Ceftazidim, Cefotaxim, Ceftriaxone, Cefixim and Cefepim as well as a mix of Amoxicillin/Clavulinate

**Inactivation of ß-Lactam-antibiotics:**

**Test results**

**Disk test**

| Antibiotic Disk | Name Test Disk | *P. paraeruginosa* ATCC 9027 | *B. spizizenii* ATCC 6633 | *E. coli* ATCC 8739 | *S. aureus* ATCC 6538 |
|---|---|---|---|---|---|
| Ampicillin 25 µg | AMP-25 | ++ | ++ | ++ | ++ |
| Sulbactam 10 µg/ Amp 20 µg | SAM-30 | ++ | ++ | ++ | ++ |
| Amxicillin 25 µg | AML-25 | ++ | ++ | ++ | ++ |
| Amoxicillin / Clavulinate 30 µg | AMC-30 | ++ | ++ | ++ | ++ |
| Piperacillin 100 µg | PRL-100 | ++ | ++ | ++ | ++ |
| Piperazillin 30 mg/ Tazobactam 10 µg | TZB-40 | ++ | ++ | ++ | ++ |
| Penicillin V 10 µg | PV-10 | ++ | ++ | ++ | ++ |
| Penicillin 10 IE | P-10 | ++ | ++ | ++ | ++ |
| Oxacillin 5 µg | Ox-5 | ++ | ++ | ++ | ++ |
| Nafcillin 1 µg | NF-1 | ++ | ++ | ++ | ++ |
| Cefazolin 30 µg | KZ-30 | ++ | ++ | ++ | ++ |
| Cephalexin 30 µg | CL-30 | ++ | ++ | ++ | ++ |
| Cephadroxil 30 µg | CFR-30 | ++ | ++ | ++ | ++ |
| Cefuroxim 30 µg | CXM-30 | ++ | ++ | ++ | ++ |
| Cefprozil 30 µg | CPR-30 | ++ | ++ | ++ | ++ |
| Ceftazidim 10 µg | CAZ-10 | + | ++ | ○ | ++ |
| Ceftazidim 30 µg | CAZ-30 | + | + | ○ | ++ |
| Cefotaxim 30 µg | CTX-30 | ++ | ++ | ++ | ++ |
| Ceftriaxon 30 µg | CRO-30 | ++ | ++ | ++ | ++ |
| Cefoxim-5 µg | CFM-5 | ++ | ++ | ++ | ++ |
| Cefpodoxim 10 µg | CPD-10 | ++ | ++ | ++ | ++ |
| Ceftiofur 30 µg | EFT-30 | ++ | ++ | ++ | ++ |
| Cefepim 30 µg | FEP-30 | ++ | ++ | ++ | ++ |
| Meropenem 30 µg | MEM-10 | ++ | ++ | ++ | ++ |

| | Recommendations for use |
|---|---|
| **Aerobic incubation** | • The closed position provides ideal incubation conditions for aerobic microorganisms<br>• Limits the dehydration of the agar during incubation<br>• For long incubation of aerobic microorganisms, the closed position is recommended<br>To lock the lid in the closed position, turn the lid clockwise into the final stop position |
| **Anaerobic incubation** | • The vent position is ideal for anaerobic incubations, as it allows an easy and effective removal of oxygen under anaerobic incubation conditions<br>• Incubate in anaerobic incubator, anaerobic jar or suitable equipment<br><br>1. First option:<br>• Turn the lid clockwise into the final stop position<br>• Turn the lid one click counterclockwise to the vent position<br><br>2. Second option:<br>Turn the lid clockwise directly into the first locked position |

| | Safety Data |
|---|---|
| **Toxic ingredients** | • None |
| **Basic composition** | • See typical composition |
| **Solvent content** | • None |
| **Safety data sheet required** | • Not mandatorily required |