

Technical Data Sheet																	
<b>Use in</b>	<ul style="list-style-type: none"> <li>Pharmaceutical Industry in clean rooms and isolators</li> <li>For industrial, laboratory &amp; research applications only</li> <li>Basic medium according to EP 2.6.13 and USP &lt;62&gt;</li> </ul>																
<b>Use for</b>	<ul style="list-style-type: none"> <li>Detection of aerobic and anaerobic micro-organism</li> <li>Contact sampling, personnel monitoring, as well as active air monitoring</li> <li>Isolation and growth of fastidious bacteria, yeasts and molds</li> <li>Especially designed for use in environments with exposure to penicillins, cephalosporins and carbapenems</li> <li><math>\beta</math>-Lactamase 2G is a broad spectrum <math>\beta</math>-lactamase which is able to inactivate penicillins, the vast majority of the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> generation cephalosporins as well as carbapenems</li> </ul> <p>The medium should be applied with a uniform and steady pressure to the surface for a few seconds. After sampling the surface must be cleaned to remove residues of the medium.</p>																
<b>Typical composition per liter</b>	<table> <tbody> <tr> <td>Casein peptone</td> <td>15 g</td> <td>Lecithin (L)</td> <td>0,7 g</td> </tr> <tr> <td>Soy peptone</td> <td>5 g</td> <td>Polysorbate 80 (T)</td> <td>5,0 g</td> </tr> <tr> <td>NaCl</td> <td>5 g</td> <td>Glycine</td> <td>2,0 g</td> </tr> <tr> <td>Agar</td> <td>15 g</td> <td><math>\beta</math>-Lactamase 2G</td> <td></td> </tr> </tbody> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Casein peptone	15 g	Lecithin (L)	0,7 g	Soy peptone	5 g	Polysorbate 80 (T)	5,0 g	NaCl	5 g	Glycine	2,0 g	Agar	15 g	$\beta$ -Lactamase 2G	
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<b>Irradiation</b>	<ul style="list-style-type: none"> <li>Irradiated at 9-20 kGy</li> </ul>																
<b>Filling volume</b>	<ul style="list-style-type: none"> <li>16-19 mL</li> </ul>																
<b>Packaging</b>	<ul style="list-style-type: none"> <li>Triple bagged, staples of 10 plates</li> <li>Transparent</li> <li>High barrier foil for H<sub>2</sub>O<sub>2</sub> as well as for water-vapor</li> <li>10 staples of 10 plates per packaging unit</li> <li>Temperature isolated handle-bag in the cardboard-boxes</li> </ul>																
<b>Units per pack</b>	<ul style="list-style-type: none"> <li>100 plates</li> </ul>																
<b>Shelf life</b>	<ul style="list-style-type: none"> <li>12 months from production date</li> </ul>																
<b>Storage conditions</b>	<ul style="list-style-type: none"> <li>Recommended storage temperature: 15-25 °C</li> <li>Should be stored at temperatures as stable as possible</li> <li>Before use: it is recommended to keep the plates upright with the agar always on the bottom</li> <li>For incubation: it is recommended to keep the plates upside down for reducing the risk of condensation dropping on the agar surface, thus affecting colonies growing on the surface</li> </ul>																
<b>Label</b>	<ul style="list-style-type: none"> <li>On the side, at the bottom part of the plate</li> </ul>																

Technical Data Sheet	
<b>Label information</b>	<ul style="list-style-type: none"> <li>• Product name: Lac 2G</li> <li>• Expiry date: YYYYMMDD → MMM in letters (e.g.: 2023Nov04)</li> <li>• Lot-number</li> <li>• Individual number</li> <li>• Barcode</li> </ul>
<b>Barcode</b>	<ul style="list-style-type: none"> <li>• 2-dimensional (data matrix), 20 digits:</li> <li>• Digits 1-3: Art.-No.</li> <li>• Digits 4-9: Lot-Number</li> <li>• Digits 10-14: Individual-Number</li> <li>• Digits 15-20: Date (YYMMDD)</li> </ul>
<b>Delivery</b>	<ul style="list-style-type: none"> <li>• Temperature controlled delivery on request</li> <li>• For shipments of larger amounts plastic pallets in Euro-size can be used</li> </ul>
<b>Petri dish</b>	<ul style="list-style-type: none"> <li>• Incubations in vent and closed position possible</li> <li>• Specific design to improve binding of agar to plate</li> <li>• Easy handling due to increased handling area</li> </ul>
<b>Locking lid</b>	<ul style="list-style-type: none"> <li>• Locking-lid contact plate, made from polystyrene</li> <li>• Inner diameter: 56.5 mm, thus providing an area of 25 cm<sup>2</sup></li> <li>• Outer diameter: 67.5 mm</li> <li>• Bottom part with 1 cm<sup>2</sup> square grid for facilitated evaluation</li> </ul>
<b>Lid positions</b>	<ul style="list-style-type: none"> <li>• All plates are delivered in the non-locked position</li> <li>• The plate contains two locked positions. If turning the lid clockwise the locked positions are in the following order:               <ol style="list-style-type: none"> <li>1. Vent position</li> <li>2. Closed position</li> </ol> </li> </ul>
<b>Aerobic incubation</b>	<ul style="list-style-type: none"> <li>• Turn the lid clockwise to the right to the end into the final stop position</li> <li>• The lid locks in the closed position</li> <li>• Ideal incubation condition for aerobic micro-organisms</li> <li>• Limits the dehydration of the agar during incubation</li> </ul>
<b>Anaerobic incubation</b>	<ul style="list-style-type: none"> <li>• The vent position is ideal for anaerobic incubations, as it allows an easy and effective removal of oxygen under anaerobic incubation conditions</li> <li>• Incubate in anaerobic incubator, anaerobic jar or suitable equipment</li> </ul> <ol style="list-style-type: none"> <li>1. First option:           <ul style="list-style-type: none"> <li>• Turn the lid clockwise to the right to the end into the final stop position</li> <li>• Turn the lid one click counter-clock-wise to the vent position</li> </ul> </li> <li>2. Second option:           <ul style="list-style-type: none"> <li>• Turn the lid clockwise directly into the first locked position</li> </ul> </li> </ol>
<b>Place of production</b>	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

Quality control, Certificates	
<b>Certificates</b>	Each lot of product can be obtained with a certificate of analysis (CoA):
	<b>Physico-chemical test parameters:</b>
	Appearance
	pH value
	Filling volume
	Irradiation
	<b>Growth Promotion test: 10-100 CFU</b>
	<i>S. aureus</i>
	<i>E. coli</i>
	<i>P. paraeruginosa</i>
	<i>B. spizizenii</i>
	<i>C. albicans</i>
<i>A. brasiliensis</i>	
<b>Test for <math>\beta</math>-lactamase Plus activity: 10.000-100.000 CFU</b>	
<i>S. aureus</i>	
No inhibition by penicillin (10 IU), Meropenem (10 $\mu$ g), Ertapenem (10 $\mu$ g), Ceftriaxon (30 $\mu$ g) and Cefazolin (30 $\mu$ g)	
<b>Sterility control</b>	No growth
<b>Certificate of origin</b>	<p>All media lots produced by PMM can be obtained with a Certificate of Origin (CoO). All animal derived raw materials are specified as follows:</p> <ul style="list-style-type: none"> <li>• Raw material</li> <li>• Tissue</li> <li>• Animal source</li> <li>• Country of origin</li> <li>• Infectivity category (acc. to TSE guideline: EMA/410/01 rev. 3)</li> </ul>
<b>BSE policy</b>	<ul style="list-style-type: none"> <li>• 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).</li> </ul>
<b>Temperature stress</b>	<ul style="list-style-type: none"> <li>• 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 comprise all regular tests which are part of the normal release test of this article (see CoA).</li> </ul>

## Quality control, Certificates

<p><b>Inactivation of <math>\beta</math>-Lactam-antibiotics:</b></p> <p><b>Test procedure</b></p>	<p>Tests for inactivation of lactam antibiotics are 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.</p> <p>Test procedure: 100<math>\mu</math>l of test suspension Mac Farland 0.5 are inoculated on a 90mm <b>TSA+LTG-<math>\beta</math>-Lactamase 2G</b> plate (art.-No. 214.0060). Test disks are applied on the plate directly after inoculation with the test strain. Tests were performed in double. Reference plate used was TSA+LTHT 90mm CSG (art. 200.0060)</p> <p><b>Result:</b> see <b>table:</b> All tested disks with <math>\beta</math>-lactam antibiotics with the exception of ceftazidime are inactivated by PMM TSA+LTG+<math>\beta</math>-lactamase 2G plate. As observed before, <i>E. coli</i> 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.</p> <p>Additional tests showed a clearly better inactivation of <math>\beta</math>-lactam antibiotics by the <b>TSA+LTG+<math>\beta</math>-Lactamase 2G</b> plates compared to older generation <math>\beta</math>-lactamase plates (like TSA+LTG+<math>\beta</math>-lactamase +) at least with the following <math>\beta</math>-lactam antibiotics: Ceftazidim, Cefotaxim, Ceftriaxone, Cefixim and Cefepim as well as a mix of Amoxicillin/Clavulinate</p>
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<p><b>Inactivation of <math>\beta</math>-Lactam-antibiotics:</b></p> <p><b>Test results</b></p> <p><b>Disk test</b></p>	<table border="1"> <thead> <tr> <th>Antibiotic Disk</th> <th>Name Test Disk</th> <th><i>P. paraeruginosa</i> ATCC 9027</th> <th><i>B. spizizenii</i> ATCC 6633</th> <th><i>E. coli</i> ATCC 8739</th> <th><i>S. aureus</i> ATCC 6538</th> </tr> </thead> <tbody> <tr><td>Ampicillin 25<math>\mu</math>g</td><td>AMP-25</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Sulbactam 10<math>\mu</math>g/Amp 20<math>\mu</math>g</td><td>SAM-30</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Amoxicillin 25<math>\mu</math>g</td><td>AML-25</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Amoxicillin / Clavulinate 30<math>\mu</math>g</td><td>AMC-30</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Piperacillin 100<math>\mu</math>g</td><td>PRL-100</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Piperazillin 30mg/Tazobactam 10<math>\mu</math>g</td><td>TZB-40</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Penicillin V 10<math>\mu</math>g</td><td>PV-10</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Penicillin 10 IE</td><td>P-10</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Oxacillin 5<math>\mu</math>g</td><td>Ox-5</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Nafcillin 1<math>\mu</math>g</td><td>NF-1</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Cefazolin 30<math>\mu</math>g</td><td>KZ-30</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Cephalexin 30 <math>\mu</math>g</td><td>CL-30</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Cephadroxil 30 <math>\mu</math>g</td><td>CFR-30</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Cefuroxim 30<math>\mu</math>g</td><td>CXM-30</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Cefprozil 30<math>\mu</math>g</td><td>CPR-30</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Ceftazidim 10 <math>\mu</math>g</td><td>CAZ-10</td><td>+</td><td>++</td><td>o</td><td>++</td></tr> <tr><td>Ceftazidim 30<math>\mu</math>g</td><td>CAZ-30</td><td>+</td><td>+</td><td>o</td><td>++</td></tr> <tr><td>Cefotaxim 30<math>\mu</math>g</td><td>CTX-30</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Ceftriaxon 30<math>\mu</math>g</td><td>CRO-30</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Cefoxim-5<math>\mu</math>g</td><td>CFM-5</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Cefpodoxim 10<math>\mu</math>g</td><td>CPD-10</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Ceftiofur 30<math>\mu</math>g</td><td>EFT-30</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Cefepim 30<math>\mu</math>g</td><td>FEP-30</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> <tr><td>Meropenem 30<math>\mu</math>g</td><td>MEM-10</td><td>++</td><td>++</td><td>++</td><td>++</td></tr> </tbody> </table>	Antibiotic Disk	Name Test Disk	<i>P. paraeruginosa</i> ATCC 9027	<i>B. spizizenii</i> ATCC 6633	<i>E. coli</i> ATCC 8739	<i>S. aureus</i> ATCC 6538	Ampicillin 25 $\mu$ g	AMP-25	++	++	++	++	Sulbactam 10 $\mu$ g/Amp 20 $\mu$ g	SAM-30	++	++	++	++	Amoxicillin 25 $\mu$ g	AML-25	++	++	++	++	Amoxicillin / Clavulinate 30 $\mu$ g	AMC-30	++	++	++	++	Piperacillin 100 $\mu$ g	PRL-100	++	++	++	++	Piperazillin 30mg/Tazobactam 10 $\mu$ g	TZB-40	++	++	++	++	Penicillin V 10 $\mu$ g	PV-10	++	++	++	++	Penicillin 10 IE	P-10	++	++	++	++	Oxacillin 5 $\mu$ g	Ox-5	++	++	++	++	Nafcillin 1 $\mu$ g	NF-1	++	++	++	++	Cefazolin 30 $\mu$ g	KZ-30	++	++	++	++	Cephalexin 30 $\mu$ g	CL-30	++	++	++	++	Cephadroxil 30 $\mu$ g	CFR-30	++	++	++	++	Cefuroxim 30 $\mu$ g	CXM-30	++	++	++	++	Cefprozil 30 $\mu$ g	CPR-30	++	++	++	++	Ceftazidim 10 $\mu$ g	CAZ-10	+	++	o	++	Ceftazidim 30 $\mu$ g	CAZ-30	+	+	o	++	Cefotaxim 30 $\mu$ g	CTX-30	++	++	++	++	Ceftriaxon 30 $\mu$ g	CRO-30	++	++	++	++	Cefoxim-5 $\mu$ g	CFM-5	++	++	++	++	Cefpodoxim 10 $\mu$ g	CPD-10	++	++	++	++	Ceftiofur 30 $\mu$ g	EFT-30	++	++	++	++	Cefepim 30 $\mu$ g	FEP-30	++	++	++	++	Meropenem 30 $\mu$ g	MEM-10	++	++	++	++
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	Safety Data
<b>Toxic ingredients</b>	<ul style="list-style-type: none"><li>• None</li></ul>
<b>Basic composition</b>	<ul style="list-style-type: none"><li>• See typical composition</li></ul>
<b>Solvent content</b>	<ul style="list-style-type: none"><li>• None</li></ul>
<b>Safety data sheet required</b>	<ul style="list-style-type: none"><li>• Not mandatorily required</li></ul>