NORDIC BIOLABS PRESENTS

Products for cleanroom

4/2022



High-quality agar plates and culture media for the pharmaceutical industry

The range includes triple packed and gamma irradiated plates, as well as single-packed plates. All plates are stored in room temperature (15-25°C), have lockable lids, and are delivered in a recyclable insulating bag and packaging.

More information on pages 3-5.

nordic biolabs

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Nordic Biolabs suppliers

Active Motif	Innovative epigenetics tools and services for research and drug discovery
AFI Groups	centrifuges for GMP and GLP environments
AGMA	Disinfection and cleaning for lab and cleanrooms
ASKION	Large system for cryo-/biobanks
BD	Antisera, media, bacteria definition
biochrom	Spectrophotometers, plate readers, plate washers
BIOCISION	Ice-free sample preparation and freezing
biosan Medical-Biological Research & Technologies	Lab instruments with small footprints
BIOSEARCH TECHNOLOGIES	Competent cells, enzymes, NGS kits etc
BRADY	Labels, printers and spill protection
byonoy	Aborbance readers with a small foot print
canvax	Buffers and Reagents for DNA/RNA
CAPRICORN SCIENTIFIC	Cell culture media and serum
Cellexus	New generation bioreactors
CELLSCRIPT™ RNA for Translation in Cells	RNA for translation in cells
Copan innovating together	Swabs, sample collection, transport
cytiva	Cell media and serum for research and drug discovery
deltalab	Tubes, sample containers and storage
FUJIFILM Value from Innovation / Wako	Biochemicals, bio-reagents, antibodies
HARRISON WIPES	Wipes for cleanroom applications
IMPLEN	Nanophotometer and cuvette photometers
INVITEK Molecular	Instruments and IVD labeled DNA/RNA kits
KiiLTO	Ethanols for desinfection
LEXOGEN	Library prep kits for RNA
Mast Group	Microbiological media, supplements
MICRONIC	Tubes in 96 well format for storage
MOLECULAR DEVICES	Plate readers, cell imaging, absorbance, fluorescence, luminescence
MP	Biochemicals, lysing matrix, homo-genizers for DNA, RNA and proteins from any tissue
Nexcelom Bioscience	Accurate, automated cell count & analysis
NUAIRE	CO_2 incubators, safety cabinets, ULT-freezers
OROCHEM Molecular Purification by Design	Chromatography consumables, sample prep for bioanalysis and proteomics
PIPETTE DOCTOR	Pipette Doctor, pipette service/accredited pipette service and calibration
pmm pharmamedia de müller gmbh	Environmental Monitoring
Promega	Cell- & molecular biology reagents, multi-mode readers and extraction systems
PROTECT 2CLEAN	Cleanroom and industrial safety products
SARTORIUS	Pipette tips, filtration and purification, pipettes, balances, centrifuges, water systems, air samplers
SHIELD Scientific	Nitrile gloves for personal protection
Statens Serum Institut	Sterilization control
Starna	Cuvettes, certified reference material
Teknokroma Professionally Friendly	Consumables and accessories for HPLC/ UHPLC, GC and SPE
TENAK	Racks for all freezer brands and models
TPP	Sterile cell culture plastics, Pipette boy (Turbofix)
vai	Contamination control and environmental monitoring
VISU	Lab furniture
xell	Serum free cell culture media for CHO, HEK, BHK and hybridoma



High-quality agar plates and culture media

Agar plates for environmental monitoring in cleanrooms

- Triple-packed and irradiated (gamma)
- H^2O^2 impermeable foil
- Stored at room temperature: 15-25°C
- Lockable lids (Click & Safe)
- Neutralizer: LTHT (L = lecithin, T = tween, H = histidine, T = Na-thiosulphate, G = Glycine)
- Long shelf life
- Temperature-controlled delivery on request
- Long incubations possible
- Unique identification of each plate by barcode label
- Contact plates and 90mm settle plates



Agar plates for environmental monitoring and selective cultural media

- Stored at room temperature: 15-25°C
- Lockable lids (Click & Safe)
- Neutralizer: LTH (L = lecithin, T = tween, H = histidine)
- Long shelf life
- Temperature-controlled delivery on request
- Long incubations possible
- Unique identification of each plate by barcode label
- Contact plates and 90mm settle plates

Cultural media in bottles

- Indicator labels for safe autoclaving
- Unique identification of each bottle with barcode label
- Volumes:
  - Infusion bottle med flip-off caps: 100ml 250ml 500ml 1000ml
  - Bottle with screw cap: 200ml 500ml 1000ml

The use of neutralizers in environmental monitoring media

Neutralizers are commonly used in pharmaceutical culture media for environmental monitoring. In Europe TSA + Lecithin, Tween 80 (Polysorbate 80), Histidine and Thiosulfate are used as the gold standard for neutralization. The exact nature and concentrations of neutralizers to gamma-irradiated media for environmental monitoring is not mentioned, neither in the EP nor in the USP. This Expertise linked to culture media formulation is hardly available outside few ready to use manufacturers.

With respect to the addition of potential neutralizers, EP 2.6.12 [1] (USP <61> in the USA) recommends some that could be used. The table “Common neutralizing agents for interfering substances” describes the most commonly used active ingredients in disinfectants and their potential inactivators:

Neutralizers→ Disinfectants↓	Sodium bisulfite	Dilution	Glycine	Lecithin	Tween	Thiosulfate	Mg^{2+}, Ca^{2+}
Glutaraldehyde	X						
Mercurials	X					X	
Phenols		X					
Alcohol		X					
Aldehydes		X	X			X	
Sorbate		X					
QAC				X	X		
Parabens				X	X		
Biguanides				X			
Iodine					X		
Halogens						X	
EDTA							X

Table 1: Common neutralizing agents and interfering substances according to the Eur. Ph.

Table 2.6-12-2 in the EP does not give any concentration of the neutralizers to be added. An indication of the concentrations to be used could be derived from the manufacturers of disinfectants, which have to provide data on the potential inactivation of their products. However, these tests are typically performed with neutralizer concentrations, which are not applicable for plated media. The typical concentration for neutralizers in agar media is: Lecithin (0,07 %) and Tween 80 (0,5%), Histidine (0,05 to 0,1 %) and Na-Thiosulfate (0,005 to 0,05 %).

Whereas Histidine and Na-Thiosulfate are well defined chemical substances, Tween and Lecithin are not. Their biological origin explains quality variations, which can significantly impact the neutralizing power of culture media if not carefully checked before routine use.

Disinfectants formulation changes over time. The manufacturers constantly innovate to propose more efficient products, challenging culture media ability to neutralize active residues. As a result, some formulas are no longer fully inactivated by the gold standard TSA-LTHT. The most recent examples in date are the Quaternary Ammonium Compounds family (QAC), active mainly against Gram positive bacteria. In a recent study [2], some QAC formulations have not been totally neutralized by LTHT. Although it is assumed that LTHT has to be used, the list provided in the Pharmacopoeia is only indicative. The presence of alternative neutralizing substances has to satisfy to 2 criteria as stated in EP 2.6.12: Neutralizing agents may be used to neutralize the activity of antimicrobial agents (Table 2.6.12.-2). They may be added to the chosen diluent or the medium preferably before sterilization. If used, their efficacy and their absence of toxicity for micro-organisms must be demonstrated [1].

Application Note: The importance of neutralizers in EM media

Pharmaceutical companies have the freedom to use alternative neutralizers, staying compliant with the regulatory texts provided that the absence of toxicity of neutralizers can be demonstrated as well as their efficacy against the disinfectants used.

TSA-U+: a game changer with the use of Quaternary ammonium compounds

The table below propose an extract TSA-U+, developed by PMM and addresses the need of an alternative neutralizer to better inactivate some of the new QAC-containing disinfectants. For the results shown below, each contact plate (TSA-LTHT article 100.0100 and TSA-U+ article 101.0100) have been inoculated with an amount of disinfectant representing 20 ml/m². After 15 min, control strains have been inoculated to each plate and incubated for 18-24 h respectively for 3-5 days for bacteria and yeasts/molds. The recovery for TSA-LTHT and TSA-U+ has been calculated versus reference plates, not treated with disinfectant (in %). The full results are available from PMM.

		TSA-LTHT			TSA-U+						
Disinfectant	**[QAC] mg/100 ml / [Biguanide] mg/100 ml**	*S.aureus*	*B.subtilis*	*S.epidermidis*	*S.aureus*	*B.subtilis*	*S.epidermidis*	*E.coli*	*Ps.aeruginosa*	*C.albicans*	*Asp.brasiliensis*
Gigasept AF 4%	876 / 0	0	0	0	92	76	83	116	97	123	99
Hexaquart forte 2%	558 / 0	0	0	0	86	106	79	92	101	97	108
Klercide Quat/Biguanide	500 / 20	0	0	0	111	109	126	105	95	112	89
Amphospray 41IP	109 / 96	0	0	0	87	93	89	85	127	127	119

Table 2: Extract of PMM study on the effect of LTHT and U+ to neutralize QAC [2] [3]

In TSA-U+ plates, Thiosulfate has been replaced by U+ as an alternative neutralizer. U+ has been shown to be a very strong inactivator of QACs or biguanides, without inhibiting microorganisms, as required by EP/USP.

Using plates with a wider neutralizing activity, may not create an immediate advantage for every user of EM plates, especially in cases where no QAC or at least no highly concentrated QAC containing disinfectant is used. However, using such plate may carry the risk of false negative results in case low concentrated QAC-disinfectants are used, where inactivation of TSA+LTHT is sometimes borderline. It allows as well choosing for a wider variety of disinfectants, for the future.

Every type of neutralizer, either LTHT or another formula, should be validated before use, using the onsite cleaning procedures, integrating both compendial strains and house flora to reflect the real conditions of use, increase product safety and reducing the burden for future validations.

[1] European Pharmacopoeia V10.0, 2.6.12: Microbial Examination of Non-Sterile Products: Microbial Enumeration Tests
[2] Neutralisation von Desinfektionsmittelrückständen, Müller et al., Pharm. Ind. 79, Nr. 9, 1298–1302 (2017)
[3] U+, The New Standard For Environmental Monitoring

PROTECT WHAT MATTERS

Cleanroom disposable from Protect2Clean

- Protective clothing – disposable clothing
- Hand protection – disposable gloves, knitted undergloves, cut resistant gloves
- Face protection – face masks and goggles
- Control mats – sticky mats
- Cleaning equipment – swabs, dry wipes, presaturated wipes, sponges, mops
- Stationary – pens, paper and tape

See some examples below



SimViz goggles
The careful design allows for long wear and maximum transpiration, offering a wide field of vision and use over all prescription eyewear. Lens, frame and strap are resistant to 40 cycles autoclave (121'C, 110kPa, 20min). The lens is replaceable. The frame is made of thermoplastic rubber which remains stable even during multiple sterilisations.



SIMTACK sticky mats
"SimTack sticky mats" consist of 30 layers of self-adhesive PE film and reliably remove particles and fibers from shoe soles and rollers. Due to the completely adhesive underside, the dust binding mats adhere securely to the floor. If the top layer is appropriately soiled, it is simply peeled off. SIMTACK sticky mats (also called Tackymat) are designed for the transition from the gray room to the clean room.



SimSafe - Disposable protective clothing for cleanrooms
The specially-developed clean-sealed technology ensures that weak points, such as seams, are thermally sealed. This provides additional barrier protection against particles and liquids.

By wearing SimSafe coveralls, no additional sleeve protectors or aprons have to be worn during the production of cytostatic drugs. The bi-component material developed for the SimSafe line dispenses completely with adhesives when connecting the carrier component and protective component. Outgassing by adhesives is therefore avoided.



Vipers – Cleanroom wipes and mops
With the Vipers brand, we provide a comprehensive range of wipes that cover every area and every use. Quality is our top priority. For example, every sterile product comes with a sterilisation certificate and every product undergoes a close-meshed incoming goods inspection.

With the Vipers brand, we also provide a comprehensive range of disposable mops. Quality is our top priority. For example, every sterile product comes with a sterilisation certificate and every product undergoes a close-meshed incoming goods inspection.



Swabs
Swabs are used to clean critical and hard-to-reach surfaces in manufacturing areas. They also play a valuable role in validating the cleaning process, particularly in the pharmaceutical industry.
Our selection includes swabs that are recommended for ISO Class 4 and 5.

PROTECT 2CLEAN



Choose the right glove for the correct level of protection

All our nitrile gloves offer the highest possible quality level = AQL 0.25.
The gloves then differs in thickness, length and content of accelerator –
all these parameters are helpful when chosing which glove to use for a specific application since this effects the level of protection.

Product	Colour	Length	Thickness	Accelator allergens	Risk level
ecoSHIELD Nitrile PF 250	Green	250 mm	0,10	Free of Thiazoles and Thiurams	Regular risk
SHIELDskin orange nitrile 260	Orange	260 mm	0,14	None	Biological risk
SHIELDskin orange nitrile 300	Orange	300 mm	0,14	None	Biological risk
SHIELD skin Chem NEO nitrle	Red	300 mm	0,31	Free of Thiurams	Chemical risk

Cleanroom gloves with lowest possible particle level

Our cleanroom gloves, SHIELDskin XTREME, are offered with three different particle levels based on how many times they have been washed in deionised water:

Branding	Process	User benefits
DI	Single washed in deionised water or multi-chlorinated	• The most economical option • Particle levels specification < 3000 per cm² ≥ 0.5 µm
DI+	Triple washed in deionised water	• The median brand option • Particle levels specification < 1200 per cm²≥ 0.5 µm
DI++	Washed several times in deionised water	• Premium offering based on extra processing • Particle levels specification < 850 per cm²≥ 0.5 µm



From this simple branding concept, you can very clearly see that washing in deionised water provides the essential differentiation in terms of cleanliness properties.

Whilst process protection is typically the main concern, increasingly users are recognising that there is often an equal need for personal protection of employees from chemicals and biohazards. To address this need, all SHIELDskin XTREME™ gloves are registered according to the PPE Regulation (EU) 2016/425.

Please contact us if you need more information.

SHIELD Scientific
compliance comfort protection

Sterilization monitoring products from Crosstex



The products are used by pharmaceutical manufacturers, medical device manufacturers, research institutes, laboratories, and life sciences/biotechnology companies.

The range offers chemical and biological indicators for;

- Steam
- Gamma irradiationE
- thylene oxide
- Dry heat
- VHP
- Chloride dioxide and other sterilization processes

CROSSTEX
A CANTEL MEDICAL COMPANY

Zyceine - Sterile Sporicide Fluid



Chlorine Releasing Agent (Hypochlorus Acid).

Effective Cleanroom sporicides are usually aggressive chemicals and whilst they can give good microbial efficacy this can often lead to corrosion problems and damage to expensive equipment.

Zyceine is a unique two component sporicide that when activated gives good microbial efficacy.

Zyceine is a totally stable product until activated.

Zyceine has a proven fungicidal efficacy of greater than a 3-log reduction in 2 minutes, and a yeasticidal efficacy greater than a 4-log reduction in 2 minutes.

- Fast acting Sporicide
- Efficacy independently validated
- WFI quality water – High Purity Water
- 1L format designed for large surface disinfection
- Fully traceable with supporting analysis
- Gamma irradiation for Sterility
- Long shelf life - Two year
- 1L pack -3 x 1LT packs per case

AGMA



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