BIOMÉRIEUX

MEDIA FILL TESTING (MFT)

Improve your MFT reading with colorimetric reagents

Your Ally in Advancing Quality

PIONEERING DIAGNOSTICS

Seamless MFT at your fingertips

Sterile manufacturing environments must be maintained during pharmaceutical manufacturing and risk management plans must ensure final product safety. Media Fill Testing (MFT) plays a pivotal role by employing a sterile microbiological growth medium, in place of the drug solution, to test whether aseptic procedures are robust enough to prevent contamination.

Through our extensive 60+ years of experience, we've learned the hard way that Media Fill testing is a time consuming bottleneck.

That's why we developed a **unique color indicator** that shifts colors[1-2] if your filled unit is contaminated, so you save valuable time and maximize accuracy.

Easy to use

Our unique color indicator changes from pink to yellow in the presence of contamination. Mitigate the risks of false positive and false negative results for MFT with easy-to-read TSB media.

Reliable

We carry out strict controls on raw materials in our dehydrated culture media manufacturing to maintain **optimal and reliable performance.** During an audit, full traceability documentation from raw materials to final product is accessible for each batch of TSB 3P for Media Fill.

MFT is under strict scrutiny and products of non-animal origin are preferred by regulatory bodies including the European Pharmacopoeia[3].

Our culture media are TSE-FREE, BSE-FREE and ANIMAL-FREE for the vegetable formulation.

Optimized performance

Our TSB 3P® Vegetable and Animal Peptones are designed

For Quick Contamination Detection

For Anaerobic and Aerobic Growth

To help guarantee a *Mycoplasma*-free product

70% of pharmaceutical companies consider personnel as the most likely source of contamination during Media Fill Testing[4].

That's why our MFT can detect skin contaminant *Propionebacterium acnes* (ATCC 6919) in as little as four days at 20-25°C.

101 wild isolates and Pharmacopoeia strains were evaluated, of which six were anaerobic.

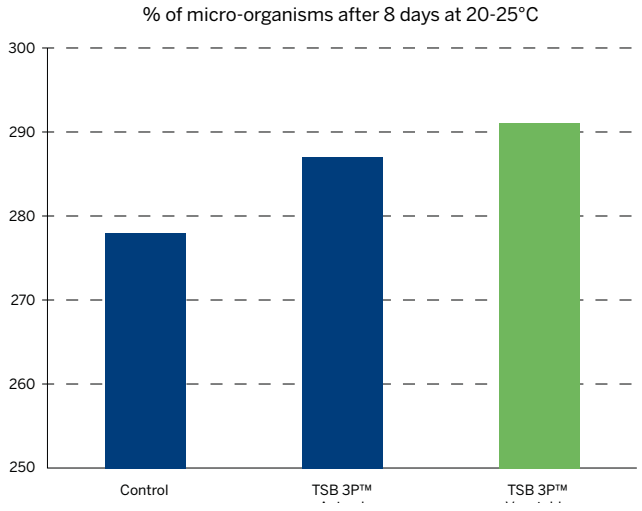

Fig 1: Growth promotion results on 95 aerobic strains after 7 days at 20-25°C. Turbidity values were summed for each micro-organism.

After 7 days at 20-25°C, both Vegetable and Animal formulations had a higher turbidity, thus a quicker detection than the control.

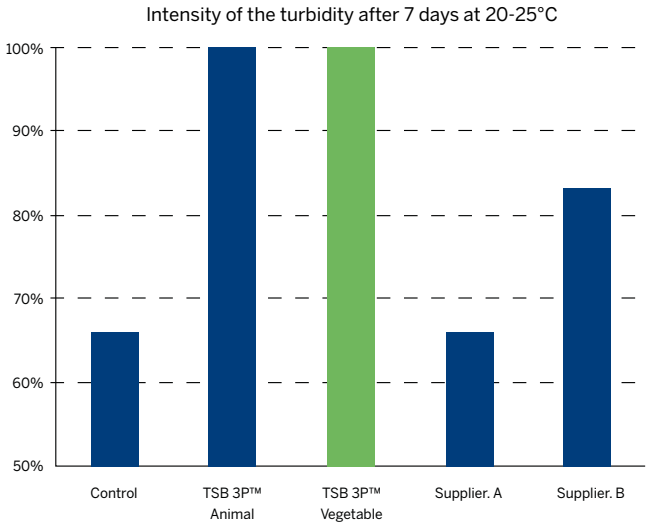

Fig 2: Proportion of the 6 anaerobic strains that grew after 8 days of incubation at 20-25°C on culture media from different suppliers.

After 8 days at 20-25°C, for both Vegetable and Animal formulations, 100% of the strains grew, whereas the control and other suppliers had much poorer performances.

References:

(1) STP Pharma Pratiques – Vol. 18, n°6, On Culture Media Relevance In Aseptic Processes Simulation.,November-December 2008.

(2) STP Pharma Pratiques – Vol. 19, n°2, Relevance Of Visual Inspection Before Incubation And Examination Of Aseptic Process Simulation Units., March-April 2009.

(3) European Pharmacopoeia, chapter 5.2.8 "Minimising The Risk Of Transmitting Animal Spongiform Encephalopathy Agents Via Human And Veterinary Medicinal Products".

(4) PDA Technical Report No. 36, Current Practices in the Validation of Aseptic Processing – 2001. PDA Journal of Pharmaceutical Science and Technology, May-June 2002; supplement TR36, Vol. 56, Number 3.

Reagents for media fill testing and environmental monitoring

	Reference	Description	Packaging
3P® CULTURE MEDIA RANGE FOR MEDIA FILL TESTING	51104	TSB 3P irradiated vegetable peptones + color indicator	500g dehydrated
	51103	TSB 3P irradiated vegetable peptones + color indicator	5kg dehydrated
	51102	TSB 3P irradiated animal peptones	500g dehydrated
	51101	TSB 3P irradiated animal peptones	5kg dehydrated
3P® CULTURE MEDIA RANGE FOR ENVIRONMENTAL MONITORING	43691 | 43699 | 420765	Irradiated COUNT-TACT® TSA 3P® with neutralizers	20 | 100 plates
	43169 | 423725	Irradiated TSA 3P® (90 mm plates)	100 plates
	43819 | 423723	Irradiated TSA 3P® with neutralizers (90 mm plates)	100 plates
	410927	Irradiated COUNT-TACT® TSA 3P® with Enhanced Neutralizers	20 plates
	43812	Irradiated COUNT-TACT® Sabouraud Dextrose Agar 3P® with neutralizers	20 plates
	43814	Irradiated Sabouraud Dextrose Agar 3P® with neutralizers (90 mm plates)	20 plates
	43288	Irradiated COUNT-TACT® TSA 3P® with neutralizers and ß-lactamase	20 plates
	43287	Irradiated TSA 3P® with neutralizers and ß-lactamase (90 mm plates)	20 plates
	421986	Irradiated R2A Agar 3P® (90 mm plates)	20 plates

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