



NordVal Certificate

Issued for:	Hygicult® TPC
NordVal No:	018
First approval date:	10 June 2005
Renewal date:	1 April 2013
Valid until:	1 April 2015

Hygicult® TPC

Manufactured and supplied by:
Orion Diagnostica Oy,
PO. Box 83,
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Finland

fulfils the requirements of the NordVal validation protocol. The reference method was NMKL No 5, 5. ed., 2001: Aerobic microorganisms and presumptive *Enterobacteriaceae*. Enumeration on surfaces and utensils.

NordVal International has studied the enclosures to the application and evaluated the results obtained in the full collaborative study published in Journal of AOAC International, 83, 1357-1365. NordVal International has concluded that it has been satisfactorily demonstrated that the requirements of the NordVal validation protocol are fulfilled. The results document no statistical difference in the performances between the Hygicult® TPC and the reference methods.

Date: 20 March 2013

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Sven Qvist'.

Sven Qvist
Chair of NordVal International

A handwritten signature in blue ink, appearing to read 'Hilde Skår Norli'.

Hilde Skår Norli
NMKL Secretary General



PRINCIPLE OF THE METHOD:

Hygicult® TPC is a hinged dip-slide culture method for the detection of total microbial count from surfaces. The slide is covered on both sides with Total Plate Count Agar which supports rapid growth of most common bacteria and fungi.

FIELD OF APPLICATION:

Hygicult® TPC slides are intended for rapid monitoring of microbiological hygiene in different types of materials, both solid and liquid. The test can be performed on-site, or the slides can be used as convenient transport media for samples.

Note: The limit values for microbial count in normal drinking water are too low to be detected by the Hygicult method.

COLLABORATIVE STUDY:

A full collaborative study on total aerobic bacterial count was conducted to validate Hygicult® TPC against NMKL method No 5 (contact plates and swabbing), using stainless-steel surfaces artificially contaminated with different microbes at various levels. Twelve laboratories participated in the collaborative study, analysing a total number of 108 samples. The study was organised by VTT Biotechnology, Finland in 1999. The following results were obtained:

Parameters	Microbial soil (low level)			Microbial soil (medium level)			Microbial soil (high level)		
	Ref method		Altern Meth.	Ref method		Altern. Meth.	Ref method		Altern. Meth.
	Contact plate	Swab-bing	TPC	Contact plate	Swab-bing	TPC	Contact plate	Swab-bing	TPC
Mean of theoretical yield (cfu/cm ²)	1.41	1.41	1.41	10.7	10.7	10.7	43.6	43.6	43.6
Mean of surface yield (cfu/cm ²)	0.43	0.43	0.35	1.91	2.17	2.07	7.12	9.09	8.03
Recovery (%)	30	30	25	18	20	19	16	21	18
Repeatability, s _r	0.17	0.32	0.15	0.70	0.81	1.45	1.94	3.04	2.51
Repeatability limit, r	0.49	0.90	0.42	1.96	2.26	4.07	5.43	8.50	7.02
Reproducibility S _R	0.21	0.38	0.20	1.29	1.45	2.02	2.99	5.07	4.29
Reproducibility limit, R	0.59	1.07	0.56	3.60	4.06	5.64	8.34	14.2	12

The Hygicult® TPC dip-slide, contact plate and the swabbing methods gave similar results at all the three microbial levels tested. There were no significant differences between results obtained at different incubation temperatures (**25 and 30 °C**) or incubation times (**48 and 72 h**) for the three methods tested.

CONCLUSION:

According to the collaborative study it can be concluded that the Hygicult® TPC dip-slide do not differ in practical terms either in yield or in precision to the reference method.