NMKL - NordVal International
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NordVal International Certificate

Issued for:	**Hygicult® TPC**
NordVal No:	018
First approval date:	10 June 2005
Renewal date:	01 February 2023
Valid until:	01 February 2025

Hygicult® TPC

Manufactured and supplied by:

Aidian
PO. Box 83, Koivu-Mankkaan tie 6B
02101 Espoo
Finland

NordVal International has studied the enclosures to the application and evaluated the results obtained in the full interlaboratory study published in Journal of AOAC International, 83, 1357-1365. The results document no statistical difference in the performances between the Hygicult® TPC and the Trypticase soy agar (TSA) culture plates and contact plates. TSA culture plates and TSA contact plates are used as reference methods.

The production of Hygicult® TPC certified according to ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes.

Date: 01 February 2023

Yours sincerely,

Hilde Skår Norli
Chair of NordVal International

Eystein Oveland
NMKL Executive Director

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 - contact plates and swabs. The test can be performed on-site, or the slides can be used as convenient transport media for samples.

HISTORY

In 2018 the data were recalculated according to the NordVal Protocol1, which complies with ISO 16140-2. As the method is a total-plate-count, determination of selectivity and limit of quantification is not relevant.

In 2022 it is noted that the study was designed according to the AOAC protocol for Official Methods of Analysis (OMA) Appendix D “Guidelines for Collaborative Study Procedures To Validate Characteristics of a Method of Analysis” and not as outlined in ISO 16140-2. The results, however, are calculated according to ISO 16140-2 and fulfill the acceptance criteria.

STUDY DESIGN

A full interlaboratory study on total aerobic bacterial count was conducted to validated Hygicult® TPC against TSA culture plates and TSA contact plates, using stainless-steel surfaces artificially contaminated with different microbes at various levels. Twelve laboratories participated in the interlaboratory study, analysing a total number of 108 samples. Samples were cultivated at 25 or 30 °C, and read after 48 hours. In addition, the samples cultivated at 25 °C were also read after 72 hours.

RELATIVE TRUENESS

For the relative trueness study, the averages of six replicates (three replicates each from two incubation temperatures (25 and 30 °C) read at 48 hours) were used as data points to form the Bland-Altman plots. The alternative method is compared against TSA contact plates (Figure 1) and against TSA culture plates (Figure 2).

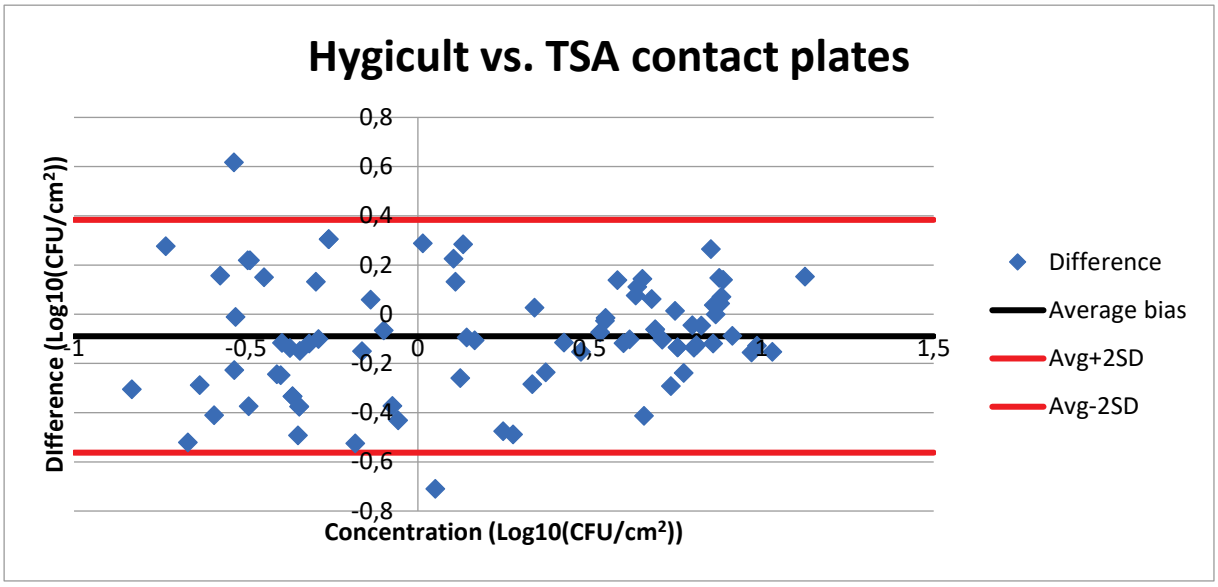

Figure 1:Bland-Altman plot for the log10-transformed difference between Hygicult TPC and TSA contact plates

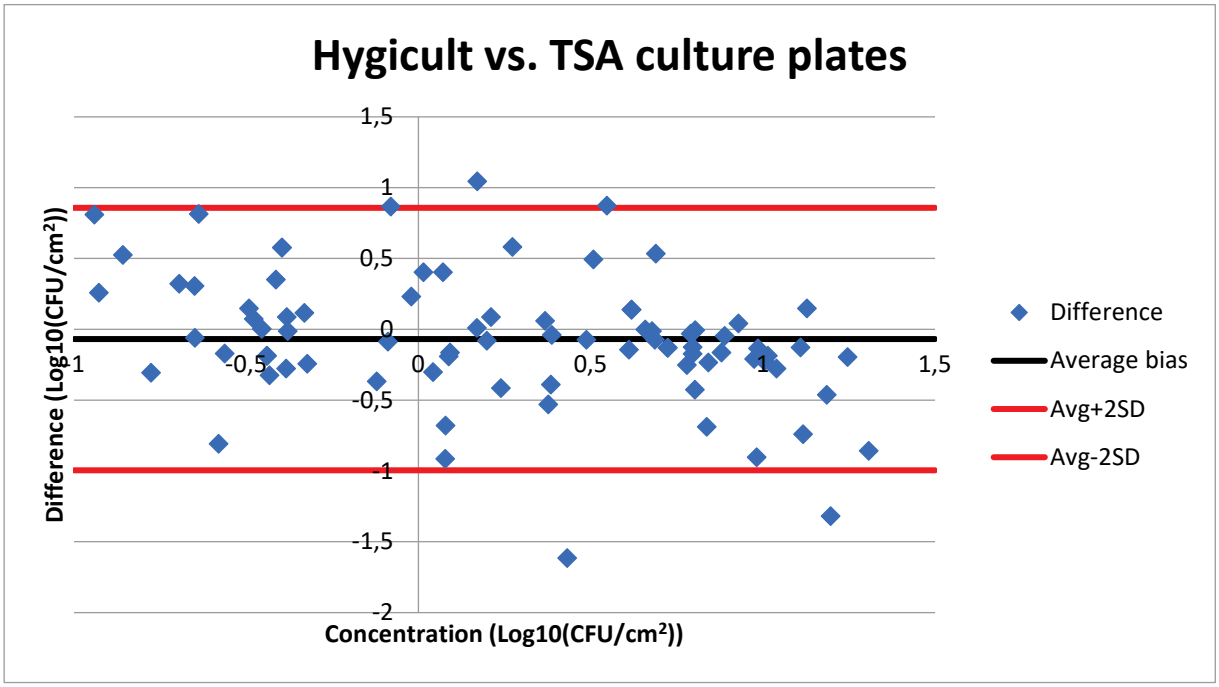

Figure 2: Bland-Altman plot for the log10-transformed difference between Hygicult TPC and TSA culture plates

The results in Figure 1 and 2 show that there is not a significant difference between Hygicult and the reference methods. As expected, no more than 5% of the results fall outside the average ± 2SD limits.

INTERLABORATORY STUDY

A full interlaboratory study on total aerobic bacterial count was conducted to validate Hygicult® TPC using stainless-steel surfaces artificially contaminated with different microbes at various levels. Twelve laboratories participated in the interlaboratory 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.
	Cont-act plate	Swab-bing	TPC	Cont-act plate	Swab-bing	TPC	Cont-act 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 (cfu/cm^2)	0.17	0.32	0.15	0.70	0.81	1.45	1.94	3.04	2.51
Reproducibility $S_{R,}$ (cfu/cm^2)	0.21	0.38	0.20	1.29	1.45	2.02	2.99	5.07	4.29

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.

Below, the results are presented in Accuracy Profiles. As six replicates were analysed, the median of the results for 25°C was used as one replicate and the median of the 30°C results as the other replicate, to get data sets with two replicates for further calculation according to the NordVal International Protocol No. 1. Results of the interlaboratory study for the comparison of Hygicult TPC to TSA contact plates (Figure 3) and to TSA culture plates (Figure 4) are shown below.

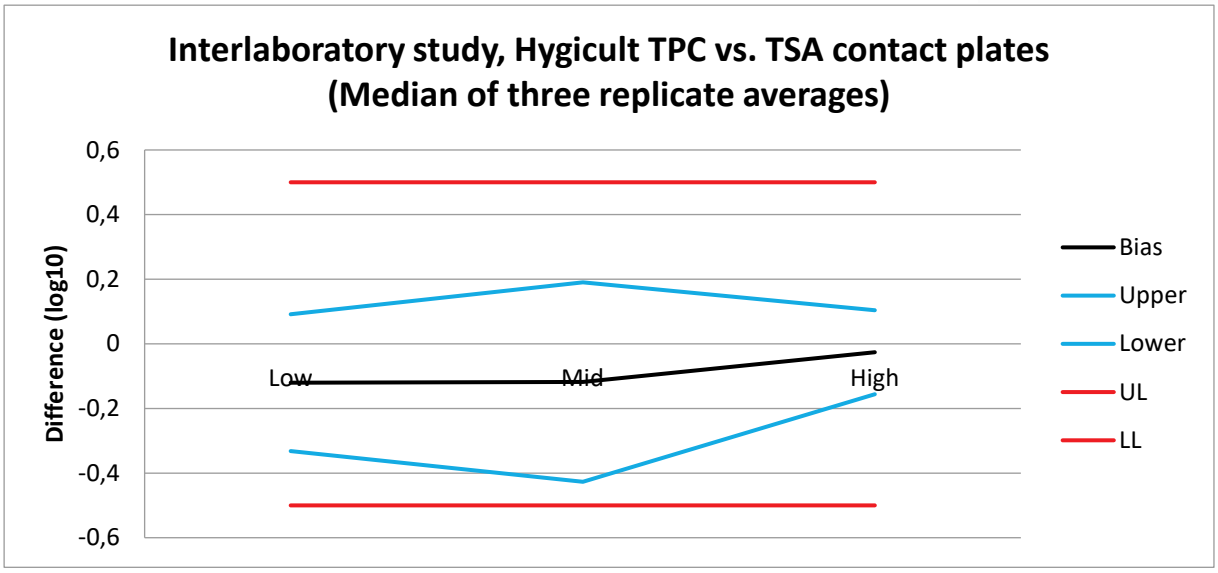

Figure 3: The results of an interlaboratory study to assess the difference between Hygicult TPC and TSA contact plates

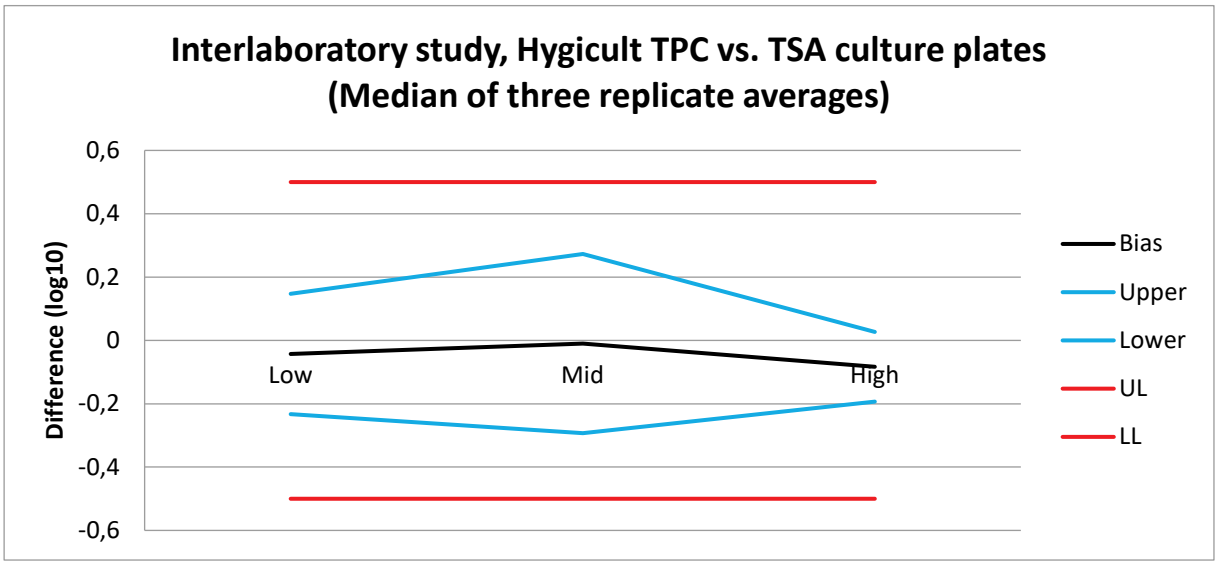

Figure 4: The results of an interlaboratory study to assess the difference between Hygicult TPC and TSA culture plates

The graphs indicate that Hygicult TPC perform equivalent to TSA culture plates and contact plates.

CONCLUSION

According to the interlaboratory study it can be concluded that the Hygicult® TPC dip-slide do not differ in practical terms ether in yield or in precision to the TSA culture plates and TSA contact plates.