



NordVal International / NMKL
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NordVal International Certificate

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|----------------------|-----------------|
| Issued for: | Hygicult® TPC |
| NordVal No: | 018 |
| First approval date: | 10 June 2005 |
| Renewal date: | 1 February 2017 |
| Valid until: | 1 February 2019 |

Hygicult® TPC

Manufactured and supplied by:
Orion Diagnostica Oy,
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 collaborative 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 reference methods.

Date: 9 February 2017

Yours sincerely

Hilde Skår Norli
Chair of NordVal International

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

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.