



HiTouch™ SCDA w/ Polysorbate 80 & Lecithin Flexi Plate™ FL035GT (γ irradiated) (Triple Pack)

Intended Use:

Recommended for determining the efficiency of sanitization of containers, equipment surfaces, water miscible cosmetics, etc. It can also be used to enumerate the organisms from water insoluble products and fatty products containing preservatives or antimicrobials.

Composition**

| Ingredients | Gms / Litre |
|---------------------------|-------------|
| Tryptone | 15.000 |
| Soya peptone | 5.000 |
| Sodium chloride | 5.000 |
| Lecithin | 0.700 |
| Polysorbate 80 (Tween 80) | 5.000 |
| Agar | 15.000 |

**Formula adjusted, standardized to suit performance parameters

Directions

Open the lid and carefully lift up the enclosed prepared medium plate so as to avoid touching the agar surface by hand. To avoid touching the agar surface by hand. Touch the surface of agar plate onto the surface to be tested. Gently press the plate manually for up to 10 seconds. Apply constant and uniform pressure to the whole surface. Replace exposed medium plate back in the base plate. Close the lid. Press the sides of the lid to make sure that it is fixed in the grooves. Disinfect the surface where the sample was taken in order to remove any possible traces of agar. Incubate the plates at specified temperature. After incubation as recommended count the number of colonies which have appeared on the surface of medium. Recommended counting range for the flexiplates is 10-100 (CFU). The number of colonies from each sample is expressed in colony forming units (CFU) extrapolated to 100 cm² of the surface sampled. According to the EU GMP Guide (1997) the values for microbiological monitoring in the operational state, for the manufacture of sterile product, the recommended limits are as follow:

| 55 mm diameter scored Touch Plate | |
|-----------------------------------|-----------|
| Grade | CFU/Plate |
| A | <1 |
| B | 5 |
| C | 25 |
| D | 50 |

*(Ref. ISO 14698-1 & 2)

Alternative Methods of inoculation :

To use as Culture plate (ii) , Sample dilution plate (iii) or Swabbing plate (iv)

The plates can be used for determination of microbial levels in liquids and fluids by dropping of 0.01 ml of sample dilution onto the medium surface.

It is also possible to inoculate this plates by moistened swab after wiping off the sample area. In case of surface with heavy contamination/ surfaces not suitable for contact plates, the swab rinse method may be used, where the swab- rinse method may be used, where the moistened swab after stroking the sample area is dipped in sterile saline and agitated. A specified amount i.e. 0.01 ml of this rinse fluid or its dilution is dropped on the surface of Flexiplates.

To use as Gravitation Settling Plate

It is also suitable for determination of airborne microorganisms in room air and other environments by gravitation settling of viable particles.

Principle And Interpretation

Tryptone and Soya peptone provide nitrogenous compounds and other nutrients essential for microbial replication. Lecithin and polysorbate 80 (Tween 80) are neutralizers reported to inactivate residual disinfectants from where the sample is collected.

Collection of samples from areas before and after the treatment with disinfectant evaluates cleaning procedures in environmental sanitation. The presence and number of microorganisms is determined by the appearance of colonies on the agar surface. After counting the colonies, carry out biochemical testing for identification.

HiTouch™ Flexiplates™ are recommended to check critical control points in protected areas while establishing or revising microbiological surface monitoring techniques and programmes in hospitals, pharma industry, food and water testing to control air, notably using an atmospheric sample collector.

Interpretation of Results:

Interpretation can vary from one laboratory to another, and each laboratory must establish its own monitoring programme.

| Classification of risk zones | Level of risk | No. of colonies per 25 cm ² (2) | No. of colonies per 100 cm ² (1) |
|--|--|--|---|
| Very low level of risk | 1 | <125 | <1000 |
| Medium level of risk | 2 | <50 | <1000 |
| High level of risk | 3 | <5 | <100 |
| Very high level of risk | 4 | <5 | <10 |
| Interpretation criteria in food industry (3,6) | | | |
| No. of microorganisms on surfaces in contact with food | Interpretation | | |
| <1/cm ² | Excellent | | |
| 2 to 10 cm ² | Good | | |
| 11 to 100 / cm ² | Surface to be cleaned rapidly | | |
| >101/ cm ² | Stop the production line and determine the cause of contamination. | | |

Type of specimen

Environment and sanitary testing, For surface examination of surfaces and for the detection and enumeration of microorganisms present on surfaces of sanitary importance.

Specimen Collection and Handling

Refer direction

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

The level of microorganisms recovery varies according to the characteristics of the surfaces and its adhesive properties (rough or smooth surfaces). HiTouch™ FlexiPlate™ is a qualitative technique for the monitoring of surface biocontamination. Taking into account the inherent inaccuracy of biological collections, it is important to use the same method of collection for all samples.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Colour

Sterile plastic plate containing light to medium amber coloured clear to slightly opalescent firm gel.

Quantity of Medium

9 ml of gel in plastic plate.

Reaction

Reaction of medium is pH 7.3±0.2

Sterility test

Sterility of the medium was checked for 14 days. Medium was found sterile without any colony formation on surface of solid medium.

Cultural response

Cultural characteristics observed after incubation at 35-37°C for 18-24 hours.

| Organism | Growth | Colour of colony |
|---|-----------|------------------------|
| <i>Escherichia coli</i> ATCC 25922 (00013*) | Luxuriant | yellow to gold |
| <i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*) | Luxuriant | Colorless |
| <i>Pseudomonas aeruginosa</i> ATCC 27853 (00087*) | Luxuriant | may have green pigment |

Key:* Corresponding WDCM numbers

Storage and Shelf Life

Store between 15 - 25°C. Use before expiry date on the label.

Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

Reference

1. Draft European Standard prEN 1632-3 (1993)
2. "Guide dublonnettoyage". Journal Officiel de la Republique Francaise. Recommendation NOE 1-90 (1991)
3. Hall L., Harnett M.J., Pub. (1964) Health Rep., 79,1021
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition
5. Murray P. R, Baron E, J., Jorgensen J. H., Pfaller M. A., Tenover F. C., Tenover R. H., (Eds.), 8th Ed., 2003, Manual of Clinical Microbiology, ASM, Washington, D.C.
6. Pryor A.K., Mc Duff C.R., Exed Housekeeper. (1969) Mass.

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Disclaimer :

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