Millipore®
Preparation, Separation,
Filtration & Testing Products

Technical Data Sheet

ICR Swab

Ordering number: 1465290100

ICR Swabs are designed for environmental monitoring of dry surfaces e.g. filling needles, tubing or other hardly to assess surfaces in cleanrooms and isolators. The principle of the test system is a qualitative presence/absence test for microbiological contamination on the tested surface.

The ICR Swabs are triple bagged and gamma-sterilized in the final packaging at a dose of 25-35 kGy. The primary and secondary sleeves consist of a multilayer material including PET and LLDPE.

The formulation of the basic medium (Soybean-Casein Digest Medium) is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia (EP, 2.6.1. and USP, 71) and supplemented with polysorbate (Tween®) 80, lecithin and pyruvate.

Mode of Action

The ICR-Swab is an all in one sample system for swabbing the surface, rinsing and incubating the swab by opening the system only once.

The ICR-Swab is based on a dual chamber system. One chamber contains the tube with the pre-moisturized swab, the second bulb chamber contains a soybean-casein digest medium supplemented with polysorbate (Tween®) 80, lecithin and pyruvate.

Both chambers are connected by the hollow shaft of the swab which is closed prior to sampling. By snapping the upper bulb chamber this closure is opened. Afterwards the culture medium can be squeezed to the swab tip.

The Swab is designed to provide the highest degree of safety for critical environments. To apply the swab, the sample system must be opened only once for swabbing the surface. All further steps such as rinsing the swab with the growth medium as well as incubation and examination are performed completely in the closed system. This assembly reduces the risk of secondary contamination by unnecessary handling.

Each ICR-Swab is labelled with the name of the product, lot number and shelf life data. Further-more the label can be imprinted with further information such as site of sampling, sampling date etc. Each tube label is provided with an individual 22-digit 2D data matrix code (digits 1-3: product code = 529; digits 4 to 9 = batch number; digits 10 to 17 = expiry date (YYYY/MM/DD); digits 18 to 22: individual swab number within batch.

The ICR-Swabs are triple-bagged and gamma-sterilized at a dose of 25-35 kGy in the final packaging. Each single swab is bagged in non-transparent, hydrogen peroxide impermeable sleeve. 10 single bagged ICR-Swabs are combined in a second non-transparent, hydrogen peroxide impermeable sleeve, which is labelled with product name, article number, lot number, expiry date, and storage temperature. These bags contain a tear notch for easy opening. A third transparent sleeve is sealed around the second layer.

The swab tip is made from knitted polyester, which minimizes the generation of particles. The swab is pre-moistened with 150 µL 0.9 % sodium chloride solution for swabbing dry surfaces. The moistening liquid does not contain any nutrients and neutralizing agents to protect the swabbed surface from a release of any growth promoting residues.

Typical Composition

Growth Medium in Bulb Reservoir (2 mL)	
Casein Peptone	17 g/L
Soy Peptone	3 g/L
Glucose Monohydrate	2.5 g/L
K_2HPO_4	2.5 g/L
NaCl	5 g/L
Polysorbate (Tween®) 80	10 mL/L
Lecithin	1 g/L
Swab-Tip: Pre-Moistening Solution (0.15 mL)	
NaCl	9 g/L

The appearance of the growth medium is clear and yellowish. The pH value is in the range of 7.1 - 7.5. The medium can be adjusted and/or supplemented according to the performance criteria required.

MERCK

Application and Interpretation

The triple packaging allows a safe transfer into the cleanrooms up to Grade A as well as into isolators. Each bag can be removed per material lock before entering the next higher cleanroom environment. The outer bag must be opened using a scissor, while the middle and inner bag can be opened easily at the tear notch. The middle and inner bag are VHP impermeable and provided with a hole for hanging them up in an isolator during VHP decontamination.

Sampling Procedure:

Remove the swab from its tube and swab the surface

Insert the swab back into its tube and snap the upper bulb containing TSB + LT

Squeeze the TSB down into the tube containing the swab

According to ISO 14698 the swab should be stroked in close parallel sweeps over the defined sampling area, while being slowly rotated. Sampling of the same area should be repeated, stroking the same swab perpendicular to the initial sweep.

After sampling the broth medium is squeezed into the tube. Used swabs should be transported and incubated in an upright position, e.g. by making use of the swab rack (order number 1.46530.0001).

The ICR Swabs are gamma-sterilized at a dose of 25 to 35 kGy with a validated SAL of 10^{-6}. Please check the broth medium within the tube immediately after sampling and before starting incubation. Turbid broth media must not be used for incubation and examination to avoid false positive results.

The TSB is supplemented with lecithin and polysorbate (Tween®) 80 to resurrect damaged organisms and to neutralize residues of several disinfectants.

Grown microorganisms out of turbid culture media should be identified.

Storage and Shelf Life

The product can be used for sampling until the expiry date if stored protected from light and properly sealed at +2 °C to +25 °C.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

Quality Control

Control Strains	ATCC #	Inoculum (CFU)	Incubation	Expected Result
Staphylococcus aureus	6538	10-100	1d at 30-35 °C	visible turbidity
Pseudomonas aeruginosa	9027	10-100	1d at 30-35 °C	visible turbidity
Bacillus subtilis	6633	10-100	3d at 30-35 °C	visible turbidity
Candida albicans	10231	10-100	2d at 20-25 °C	visible turbidity
Aspergillus brasiliensis	16404	10-100	3d at 20-25 °C	visible turbidity

Please refer to the actual batch related Certificate of Analysis.

Literature

European Pharmacopoeia 9.3 (2018): 2.6.1 Sterility Tests.

ISO 14698-1:2003: Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods.

PDA Technical Report No. 13 (2014 Revised): Fundamentals of an Environmental Monitoring Program.

Sandle, T. (2011): A study of a new type of swab for the environmental monitoring of isolators and cleanrooms (the Heipha ICR-Swab). European Journal of Parenteral and Pharmaceutical Sciences. 16(2): 42-48.

United States Pharmacopoeia 40 NF 35 (2017): <71> Sterility Tests; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.

To place an order or receive technical assistance

In Europe, please call Customer Service:
France: 0825 045 645
Germany: 069 86798021
Italy: 848 845 645
Spain: 901 516 645 Option 1
Switzerland: 0848 645 645
United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840
Or visit: **MerckMillipore.com/offices**
For Technical Service visit: **MerckMillipore.com/techservice**

MerckMillipore.com

Lit. No. MK_DS1702EN Ver. 1.0
2018 - 10015
02/2018