

Technical Data Sheet

IsoBag® TSA Settle

Ordering number: 1.46814.0080

The IsoBag® TSA Settle is designed for quick and convenient transfer of culture media for air monitoring into isolators or RABS systems containing Getinge DPTE® Alpha Ports of 190 mm diameters. The plate can be transferred into the isolator without the need for additional decontamination of the outside packaging of plates. The product allows increased production time by decreased requirements for decontamination cycles, e.g. in case of campaign productions. Furthermore, this procedure will save space for storage of culture media in the isolator.

The IsoBag® TSA Settle is a sterile polyurethane DPTE® Beta Bag compatible with 190 mm DPTE® Alpha Ports and filled with:

8 packs of 10 single bagged, 90 mm settle plates (article 146001 – TSA ICR) and

4 x 5 single bagged, pre-sterilized zip bags for safe transport of used plates into non-controlled areas for incubation and colony counting.

The filled IsoBag® product is double bagged and irradiated at a dose of 10-20 kGy.

Typical Composition of Included Settle Plates

Ingredient	Amount per liter
Casein Peptone	15 g/l
Soy Peptone	5 g/l
NaCl	5 g/l
Agar	15 g/l

The appearance of the 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.

Application and Interpretation

The plates are introduced into isolators or RABS by connecting the IsoBag® Beta Port to a 190 mm DPTE® Alpha Port. Therefore, please follow the instructions for use of Getinge for the DPTE® bidirectional transfer system. The integrity of the bag remains stable up to 14 connections to the Alpha Port.

Single packs of plates may be transferred into the isolator by the possibility of multiple connections. Up to 14 connections of the IsoBag® lid with the Alpha Port are possible. Please do not open the IsoBag® lid outside of the isolator or RABS if further connections to the Alpha Port will be performed.

There is no need to decontaminate the plates, which were transferred into the isolator. If the packaging of plate packs is not damaged a VHP decontamination is allowed, however. Multiple connections can be performed only if no contamination is observed within the isolator.

For the use of the included settle plates for active or passive air monitoring within the isolator please refer to the Technical Data Sheet of Tryptic Soy Agar – ICR in 90 mm, settle plates (article 146001).

For transfer of used plates to the incubator up to 8 settle plates may be packed into the zip bags included in the IsoBag® packaging. The outtake can be performed by a new, sterile DPTE® Beta Bag from Getinge or by using an empty IsoBag® Beta Bag, if the maximum connection number of 14 has not been applied before.

Storage and Shelf Life

The product can be used for sampling until the expiry date if stored upright, protected from light and properly sealed at +15°C to +25°C. The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

Condensation can be prevented by avoiding quick temperature shifts and mechanical stress.

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

Please refer to the actual batch related Certificate of Analysis as well as the batch related Certificate of Analysis of the included batch of Tryptic Soy Agar – ICR in lockable, 90 mm settle plates (article 146001 - download from webpage using either 1460010020 or 1460010120 combined with the concerned batch number of included plates).

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