

Technical Data Sheet

IsoBag® TSA Settleplus

Ordering number: 1.46822.0080

The IsoBag® TSA Settleplus is designed for quick and convenient transfer of culture media for air monitoring into isolators or RABS installations containing Getinge La Calhène DPTE® Alpha Ports of 190mm diameter. 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 Settleplus is a sterile polyurethane DPTE® Beta Bag (DPTE is a trademark by Getinge La Calhène) compatible with 190mm DPTE® Alpha Ports and filled with:

- 8 packs of 10 single bagged, lockable 90mm settle plates (article 146685 – TSA ICRplus)
- 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® is double bagged and irradiated at a dose of 10-20 kGy.

Further IsoBag® designs are available with the identical media formulation

- IsoBag® TSA Settle (article number 1468140080): 190 PU DPTE Beta Bag filled with 8x10 single bagged settle plates (article number 146001) and 4x5 single bagged, pre-sterilized zip-lock transport bags. The product is intended for microbial air monitoring in isolators and RABS. The plate design allows aerobic incubation only.

Typical Composition

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.

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Application and Interpretation

The plates are introduced into isolators or RABS by connecting the IsoBag® Beta Port to a 190mm DPTE® Alpha Port. Therefore please follow the instructions for use of the Getinge La Calhène 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® 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 that are transferred into the isolator. If the packaging of the plates is not damaged a VHP decontamination is allowed. 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 – ICRplus 90mm Settle Plates (article 146685).

For transfer of used plates out of the incubator, up to 4 settle plates may be packed into the zip bags included in the IsoBag®. The transfer out of the isolator 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 reached prior.

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 for Pharma

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 – ICRplus 90mm settle plates (article 146685 – download from webpage using either 1466850020 or 1466850120 combined with the respective batch number of the included plates).