Technical Data Sheet

IsoBag™ TSA + LTHTh Contact

Ordering number: 1.46754.0100

The IsoBag™ TSA + LTHTh Contact is designed for quick and convenient transfer of culture media for surface monitoring into isolators or RABS systems containing Getinge La Calhène DPTE® Alpha Ports of 190 mm diameters. The plates can be transferred into the isolator without the need for additional decontamination of the outside packaging of plates. The product allows optimized 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 + LTHTh Contact is a sterile polyurethane DPTE® Beta Bag (DPTE is a trademark by Getinge La Calhène) compatible with 190 mm DPTE® Alpha Ports and filled with:

- 10 packs of 10 single bagged, 55 mm contact plates (article 146231 – – TSA Contact + LTHTh 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™ is double bagged and irradiated at a dose of 10-20 kGy.

Further plate designs are available with the identical media formulation:

- IsoBag™ TSA+LTHTh Settle$_{plus}$ (article number 1467550080): 190 PU DPTE® Beta Bag filled with 8 x 10 single bagged, lockable settle plates (article number 146683) and 4 x 5 single bagged transparent, zip-lock transport bags. The product is intended for microbial monitoring of air (passive and active) in isolators and RABS. The plate design allows aerobic, anaerobic and microaerophilic incubation.
- IsoBag™ TSA+LTHTh Settle (article number 1467560080): 190 PU DPTE® Beta Bag filled with 8 x 10 single bagged settle plates (article number 146069) and 4 x 5 single bagged transparent, zip-lock transport bags. The product is intended for microbial monitoring of air (passive and active) in isolators and RABS. The plate design allows aerobic incubation only.

Typical Composition of included contact plates

Casein Peptone	15 g/l
Soy Peptone	5 g/l
NaCl	5 g/l
Polysorbate (Tween®) 80	5 ml/l
Lecithin	0.7 g/l
Histidine	0.5 g/l
Sodium thiosulfate	0.5 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. (Tween is a trademark of ICI Americas Inc.)

Application and Interpretation

The plates are introduced into isolators or RABS by connecting the IsoBag™ to a 190 mm DPTE® Alpha Port. Therefore please follow the instructions for use of Getinge La Calhène 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™ with the Alpha Port are possible. Please do not open the IsoBag™ 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. As long as the packaging of plate packs is not damaged a VHP decontamination is allowed, however.

For the use of the included contact plates for surface monitoring within the isolator please refer to the Technical Data Sheet of TSA Contact + LTHTh ICR in 55 mm contact plates (article 146231).

For transfer of used plates to the incubator the contact plates may be packed into the zip lock bags included in the IsoBag™. The outtake can be performed by a new DPTE® Beta Bag from Getinge La Calhène or by using an empty IsoBag™, 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.

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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 Contact Agar + LTHTh ICR in 55 mm contact plates (article 146231 – download from webpage using either 1462310020 or 1462310200 combined with the concerned batch number of included plates).

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