Trypcase Soy Irradiated agar (TSIR)

For microbiological control only

A irradiated, triple-wrapped medium for the monitoring of microbial contamination in clean rooms

SUMMARY AND EXPLANATION

The Trypcase Soy Irradiated agar is intended for the monitoring of microbial contamination in hospital and industrial clean rooms.
This agar is recommended (1):
- for sampling air using an air sampler,
- for static sampling of ambient air,
- for environmental sampling (gloves, fingers etc.).

The formula conforms to the specifications of the B medium of the European pharmacopoeia (2) and to the USP (3).

PRINCIPLE

The Trypcase Soy Irradiated agar plates are triple-wrapped in cellophane packets, enabling removal of each layer in the airlock of the protected area.
The presence of an irradiation indicator enables rapid and easy visual confirmation by the clean room operator that the medium is irradiated.
Each pack (media and their wrappings) is irradiated at a recorded dose between 8 and 12 kGray to guarantee that no viable contaminants are present. The minimum dose is sufficient to guarantee that there are no viable contaminants in the media and their wrappings. The maximum dose does not modify the performance of the medium.

CONTENT OF THE KIT

	Ready-to-use media
REF **43131**	Pack of 2 x 10 plates (90 mm) Triple-wrapped in 10's
REF **43557**	Pack of 10 x 10 plates (90 mm) Triple-wrapped in10's
REF **43556**	Pack of 4 x 5 plates (140 mm) Triple-wrapped in 5's
	TSIR *

* printed on each plate

COMPOSITION

Theoretical formula

This medium can be adjusted and/or supplemented according to the performance criteria required:

Casein peptone (bovine)	15 g
Soy peptone	5 g
Sodium chloride	5 g
Agar	15 g
Purified water	1 L

pH 7.3

MATERIAL REQUIRED BUT NOT PROVIDED

- Bacteriology incubator.

POSSIBLE ADDITIONAL MATERIAL

- ***air IDEAL*® 3P™ Traceability** air sampler (Ref. 410175).
- BI-BOX 90 (Ref. 96311).

WARNINGS AND PRECAUTIONS

- **For microbiological control only.**
- **For professional use only.**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- All specimens, microbial cultures and inoculated products should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the bacterial group studied should be observed throughout this procedure. Refer to "CLSI® M29-A, *Protection of Laboratory Workers from Occupationally Acquired Infections*; *Approved Guideline* - Current Revision". For additional information on handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories – CDC/NIH – Latest edition", or the current regulations in the country of use.
- Culture media should not be used as manufacturing material or components.
- Do not use reagents after the expiry date.
- Do not use reagents if the packaging is damaged.
- Do not use contaminated plates or plates that exude moisture.
- The medium should be used according to the procedure indicated in this package insert. Any change or modification in the procedure may affect the results.

STORAGE CONDITIONS

- **Store the plates in their box at 2-8°C until the expiry date.**
- **The plates can be stored for 5 days at room temperature in the cellophane sachet.**

SPECIMENS

Follow the recommendations in the current standards to perform specimen collection and preparation.

INSTRUCTIONS FOR USE

1. **Allow the plates to come to room temperature.**
2. Open the pack and remove the first layer of wrapping in the airlock of the protected area.
3. Remove the two remaining layers of wrapping in the protected area. The plates are treated by irradiation. Consequently, there is no need to sterilize or incubate them prior to entry into the clean room.

4. Inoculating the plate:
   - For dynamic air sampling, collect using an air sampler. Refer to the package insert for the device used.
   - For passive air sampling: expose the agar to the air in the room or under a laminar flow hood for up to 4 hours (sedimentation method).
   - For environmental sampling (gloves, fingers etc.), use 140 mm plates.
5. As a guideline only, plates can be incubated for 2 to 3 days at 25-30°C for mesophilic bacteria, and if required, a further 3 days at room temperature in daylight for stressed bacteria. The user is responsible for choosing the appropriate temperature for the intended use, in accordance with current standards. Incubation time varies according to the type of specimen and the microorganisms being tested for.

Notes:

- After step 3, the sterile Bi-Box 90 can be used for safer transport of 90 mm plates between the sampling site and the laboratory.
- The 90 mm plates can be incubated directly in the Bi-Box 90.

READING AND INTERPRETATION

- After incubation, observe the bacterial growth.
- Count the colonies. Automatic enumeration is possible as the ink-coding is printed on the side of the plate.
- The user is responsible for interpretation. It is recommended to establish alarm levels and levels which require user intervention, in order to take the most appropriate corrective action (4).

QUALITY CONTROL

Trypcase Soy Irradiated agar is designed and developed to meet the strictest quality requirements.
The results of the strains tested in the batch by batch quality control are given on the quality control certificate available on the technical library that can be accessed via our corporate website (www.biomerieux.com).

LIMITATIONS OF THE METHOD

- Growth depends on the requirements of each individual microorganism. It is therefore possible that certain strains which have specific requirements, (growth factors, temperature, incubation conditions etc.) may not develop.
- Given the wide variety of specimens tested, it is the responsibility of the user to validate this medium for its specific intended use.

WASTE DISPOSAL

Unused reagents may be considered as non-hazardous waste and disposed of accordingly.
Dispose of all used reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

1. ISO 14698-1 (2003) – Cleanrooms and associated controlled environments. Biocontamination control. Part 1 : general principles and methods.
2. European Pharmacopoeia EP *.
3. United States Pharmacopoeia USP *.
4. ASPEC – Guide Paris octobre 2002.

* This document is in compliance with current version of Pharmacopoeias.

INDEX OF SYMBOLS

Symbol	Meaning
	Catalogue number
	Manufacturer
	Temperature limit
	Use-by date
	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests

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