Irradiated Tryptic Soy 3P™ Agar (TSA3P)

For laboratory use only

INTENDED USE
Triple-wrapped irradiated medium for the monitoring of microbial contamination in cleanrooms and isolators.

SUMMARY AND EXPLANATION
Irradiated Tryptic Soy 3P™ Agar is used for the monitoring of microbial contamination in industrial and hospital cleanroom environments.

This agar is intended for:[1]

- Sampling air using an air sampler.
- Static sampling of ambient air.
- Controlling equipment and personnel (gloves, fingers, etc.).

The formula complies with the medium described in the harmonized chapters of the European, United States, and Japanese Pharmacopoeia.[2,3,4]

PRINCIPLE OF THE TEST
Irradiated Tryptic Soy 3P Agar is triple-wrapped in stacks of ten plates, which allows the removal of each wrap as the plates are taken further into the cleanroom.

The presence of an irradiation indicator enables the rapid and easy visual confirmation by the cleanroom operator that the medium is irradiated.

Each pack (media and their wrappings) receives an irradiation dose between 13 and 22 kGy to guarantee that no viable contaminants are present.

Specific 3P media packaging has been designed to be resistant to Vaporous Hydrogen Peroxide (VHP) and Peracetic Acid (PA) gassing cycles as part of an isolator decontamination cycle. As such, this media is appropriate for use in isolators as part of the environmental monitoring program

Use of the medium was validated in real time over the duration of the product's shelf-life after exposure for 4 hours under a laminar flow hood.

CONTENT OF THE KIT

Irradiated Tryptic Soy 3P™ Agar		
REF	**Ready-to-Use Medium (TSA3P printed on each plate)**	
410251	Pack of 2x10 plates (90 mm) triple-wrapped in stacks of 10	Σ = 20
418140	Pack of 10x10 plates (90 mm) triple-wrapped in stacks of 10	Σ = 100

COMPOSITION
Theoretical formula:

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

Enzymatic casein peptone (bovine)	15 g
Enzymatic soy peptone	5 g
Sodium chloride	5 g
Agar	15 g
Purified water	1000 ml

pH 7.3

ADDITIONAL MATERIALS REQUIRED BUT NOT PROVIDED
Reagent:
- Air sampler: air IDEAL® 3P™ Traceability (REF 410175)

Material:
- Bacteriology incubator

STORAGE INSTRUCTIONS
Store the plates in their box at 2-25°C until the expiration date.

WARNINGS AND PRECAUTIONS
1. **For laboratory use only**.
2. **For professional use only.**
3. 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).
4. 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-A3, *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline* – Third Edition."[5] For additional information on handling precautions, refer to the latest edition of *Biosafety in Microbiological and Biomedical Laboratories*,[6] or the current regulations in the country of use.
5. Culture media should not be used as manufacturing material or components.
6. Do not use reagents after the expiration date.
7. Do not use reagents if the packaging is damaged.
8. Do not use contaminated plates or plates that exude excessive moisture.
9. 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.

SPECIMENS
Follow the procedures currently in use in the laboratory for specimen collection.

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 cleanroom airlock.
3. Remove the second and third layers of wrapping in the cleanroom. The plates are treated by irradiation. Consequently, there is no need to sterilize or incubate them prior to entry into the cleanroom.
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 (settle-plate method).
   - For controlling equipment and personnel (gloves, fingers, etc.), refer to the current practices employed in the laboratory.

Once sampling has been completed, the LockSure® plate can be optionally locked to secure the plate during transport and incubation steps. To lock the plate, replace the lid on the base and gently turn the lid clockwise until the locking mechanism is engaged. Reverse this operation to release the lid again as necessary.

5. For incubation, follow the recommendations in the harmonized chapters of the Pharmacopoeia.[2,3,4] For the detection of total aerobic flora, the optimum incubation temperature is 30-35°C.

   The user is responsible for choosing the appropriate incubation time and temperature for the intended use, in accordance with current standards.

READING AND INTERPRETATION

1. After incubation, observe the microbial growth and count the colonies.
2. The user is responsible for interpretation. It is recommended to establish alarm levels and levels that require user intervention, in order to take the most appropriate corrective action.[2,7]

QUALITY CONTROL

Irradiated Tryptic Soy 3P 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. This is available on the technical library that can be accessed via our corporate website (www.biomerieux.com/techlib).

LIMITATIONS OF THE METHOD

1. Growth depends on the requirements of each individual microorganism. It is therefore possible that certain strains with specific requirements (growth factors, temperature, incubation conditions, etc.) may not develop.
2. After exposure for 4 hours under a laminar flow hood or in an air sampler, small cracks may appear at the periphery of the agar. They do not affect the development of the strains.
3. Given the wide variety of specimens tested, it is the responsibility of the user to validate this medium for its specific intended use.
4. A slight change in the pH of the agar may be observed with time, but does not affect performance.

WASTE DISPOSAL

Unused reagents may be considered as non-hazardous waste and disposed of accordingly. Dispose of all used reagents and 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.

REFERENCES

1. ISO 14698-1 (2003). Cleanrooms and associated controlled environments. Biocontamination control. Part 1: General principals and methods.
2. United States Pharmacopeial Convention, Inc. *The United States Pharmacopeia 37/The National Formulary 32*, Supp. 1, February 1, 2014, online.
3. Japanese Ministry of Health, Labour and Welfare. *The Japanese Pharmacopoeia*, 16th ed., March 24, 2011, online.
4. European Pharmacopoeia Commission, Council of Europe European Directorate for the Quality of Medicines (EDQM). *The European Pharmacopoeia*, 8th Main Edition (8.2), July 15, 2013, online.
5. Clinical and Laboratory Standards Institute. 2005. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – M29-A3. CLSI, Wayne, PA.
6. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health. 2007. *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 5th Edition. US Government Printing Office, Washington, D.C.
7. EC Guide to Good Manufacturing Practices (2003) – Annex I: Manufacture of Sterile Medicinal products.

INDEX OF SYMBOLS

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

WARRANTY

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For technical assistance in the USA, contact bioMérieux Customer Service at 1-800-682-2666. Outside the USA, contact your local bioMérieux representative.

Instructions for use provided in the kit or downloadable from www.biomerieux.com/techlib

REVISION TABLE

This section contains a summary of changes made to each released revision of this document starting with part number 9308178 A.

Release Date	Part Number	Change Type	Change Summary
2014-09	9308178 A	N/A	Creation of new document.

NOTE: Minor typographical, grammar, and formatting changes are not included in the revision history.

Change Type categories:
- **N/A =** Not applicable
- **Correction** = Correction of documentation anomalies.
- **Technical Change** = Addition, revision and/or removal of information related to the product.
- **Administrative** = Implementation of non-technical changes noticeable to the user.

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