REF 410250, 418049

9308177 **A** – 2014-06 EN

Count-Tact® (CT3P)

Irradiated Tryptic Soy Agar with L&P80

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 Agar with L&P80 (lecithin and polysorbate 80) is used for the monitoring of microbial contamination in industrial and hospital cleanroom environments.

This agar is intended for:[1]

- Monitoring surfaces, equipment, and personnel by applying the agar manually.
- Monitoring air using an air sampler.

Use of a contact method to control surfaces is recommended in the ISO standards 14698-1,[1] ISO 18598,[2] USP chapter 1116,[3] and in Good Manufacturing Practices.[4,5]

PRINCIPLE OF THE TEST

Irradiated Tryptic Soy Agar with L&P80 is triple-wrapped in stacks of ten plates, which allows the removal of each wrap as the plates are taken further into the cleanroom. Each plate has a diameter of 65 mm and a grid scored on the base.

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.

The convex agar meniscus allows direct application to the test surface, such as walls, floors, utensils, or employees, for hygiene monitoring.

The medium contains a mixture of peptones to enable optimum growth of the microorganisms encountered in the pharmaceutical environment.

The medium also contains four neutralizing agents to inactivate any residual disinfectants present on the surface to be tested, and therefore enables comparative tests before and after disinfection:

- The combination of lecithin and polysorbate 80 neutralizes aldehydes and phenolic compounds.
- The combination of lecithin and polysorbate 80 neutralizes the quaternary ammonium compounds.
- The polysorbate 80 neutralizes hexachlorophene and mercurial derivates.
- Lecithin neutralizes chlorhexidine.

CONTENT OF THE KIT

Irradiated Tryptic Soy Agar with L&P80		
REF	Ready-to-Use Medium (CT3P printed on each plate)	
410250	Pack of 2x10 plates (65 mm) triple-wrapped in stacks of 10	Σ = 20
418049	Pack of 10x10 plates (65 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.

Casein peptone (bovine)	15.0 g
Soy peptone	5.0 g
Sodium chloride	5.0 g
Soy lecithin	0.7 g
Polysorbate 80	5.0 g
Agar	20.5 g
Purified water	1000 ml

pH 7.3

ADDITIONAL MATERIALS REQUIRED BUT NOT PROVIDED

Reagent:

- Air sampler: air IDEAL® 3P™ (REF 96303) or air IDEAL 3P Traceability (REF 410174)

Material:

- Bacteriology incubator

STORAGE INSTRUCTIONS

1. Store the plates in their box at 2-25°C until the expiration date.
2. The plates show minimum water condensation when stored at 15-25°C.

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."[6] For additional information on handling precautions, refer to the latest edition of *Biosafety in Microbiological and Biomedical Laboratories*,[7] 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

Sample collection frequency and the number of measurement points can be defined according to a microbiological environmental monitoring program or the Quality Assurance procedures in operation in the company or health establishment.

Samples must be collected on dry surfaces.

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.

   If the media is to be used in a gassing isolator, the external wrap should be removed prior to transfer of the plates into the gassing chamber to minimize the risk of introducing contaminants and particulate matter. The media with two remaining wraps has been validated for exposure to VHP, or PA decontamination cycles in isolators, without altering the culture media performance.
3. Remove the second and third layers of wrapping once inside 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 sampling of surfaces, equipment or personnel, apply the agar directly onto the surface to be tested, ensuring that an even pressure is distributed over the whole plate for 10 seconds.
   - For dynamic air sampling, collect using an air sampler. Refer to the package insert for the device used.
5. Clean the surface where the sample was taken in order to remove any possible traces of agar.
6. Incubate the plate.

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

NB: The plates must be incubated with the lid uppermost.

READING AND INTERPRETATION

1. After incubation, observe the microbial growth and count the colonies.
2. The mean surface area of the plate is 25 cm^2.
3. 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 Agar with L&P80 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. The level of microorganism recovery varies according to the characteristics of the surface and its adhesive properties. Taking into account the inherent inaccuracy of biological samples, it is important to use the same method of collection from one sample to another.
3. The agents in the medium that neutralize anti-bacterial activity have been selected to enable the detection of organisms in specimens containing antiseptics and/or usual preservatives. Given the large variety of antiseptics and preservatives available on the market, it is recommended to check that the culture medium effectively neutralizes the ones you use.
4. Given the wide variety of specimens tested, it is the responsibility of the user to validate this medium for its specific intended use.
5. 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 principles and methods.
2. ISO 18593 (2004). Microbiology of food and animal feeding stuffs - Horizontal methods for sampling techniques from surfaces using contact plates and swabs.
3. USP chapter 1116: microbiological evaluation of cleanrooms and other controlled environments.
4. EC Guide to Good Manufacturing Practices (2003) - Annex I: Manufacture of Sterile Medicinal Products.
5. Guidance for Industry Sterile Drug Products Produced by Aseptic Processing (2004) – Current Good Manufacturing Practice.
6. Clinical and Laboratory Standards Institute. 2005. *Protection of Laboratory Workers from Occupationally Acquired Infections*; Approved Guideline – M29-A3. CLSI, Wayne, PA.
7. 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.

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

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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 9308177 A.

Release Date	Part Number	Change Type	Change Summary
2014-06	9308177 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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