



10 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, it is responsibility of the end-user to perform Quality Control testing in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed some test strains useful for the quality control of medium.

CONTROL STRAINS	INCUBATION T° / t / ATM	EXPECTED RESULTS
S.Typhimurium ATCC 14028	35-37°C / 18-24h / A	good growth after subculture to TSA plate
<i>E.coli</i> ATCC 25922	35-37°C / 18-24h / A	scanty growth after subculture to TSA plate

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection

11 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of ready to use tubes of Muller Kauffmann Tetrathionate Broth and of the raw material used for the production of prepared tubes (dehydrated Muller Kauffmann Tetrathionate Broth Base REF 401743 supplemented with brilliant green and iodine solutions), are tested for productivity and selectivity by comparing the results with a previously approved Reference Batch.

Productivity is tested by dilution to extinction method, by inoculating 1 mL of appropriate decimal dilutions of target organisms in test tubes and incubating at 35-37°C for 18-24 hours and recording the highest dilution showing growth in Reference Batch (G_{RB}) and in Test Batch (G_{TB}) after sub-culture on Tryptic Soy Agar plates. Productivity is tested with the following target strains: S.Typhimurium ATCC 14028, S.Enteritidis ATCC 13076. The productivity index $G_{RB}-G_{TB}$ for each test strain shall be ≤ 1 .

Selectivity is evaluated with dilution to extinction method, by inoculating 1 mL of appropriate decimal dilutions of non-target organisms in duplicate test tubes and incubating at 35-37°C and at 42-43°C for 18-24 hours and recording the highest dilution showing growth in Reference Batch (G_{RB}) and in Test Batch (G_{TB}) after sub-culture on Tryptic Soy Agar plates. Selectivity is tested with the following non-target strains: *E.coli* ATCC 25922, *E.faecalis* ATCC 29212. The selectivity index $G_{RB}-G_{TB}$ for each test strain shall be ≥ 1 .

Productivity and selectivity are tested also together with a mixture of appropriate dilutions of target and non-target strains: S.Typhimurium ATCC 13076+*E.coli* ATCC 25922+*P.aeruginosa* ATCC 27853. After incubation of inoculated tubes at 35-37°C and at 42-43°C for 18-24 hours and subculture on XLD Agar plate, the target strain will show a predominant growth on plated medium.

12 - LIMITATIONS OF THE METHOD

- Muller Kauffmann Tetrathionate Broth is not suitable for growth of S.Typhi, S.Paratyphi, S.Sendai, S.Gallinarum; it is not recommended for examination of typhoid fever.⁵
- After the enrichment in Muller Kauffmann Tetrathionate Broth, even if the microbial colonies on the plates are differentiated on the basis of their morphological and chromatic characteristics, it is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on isolates, from pure culture, for complete identification. If relevant, perform antimicrobial susceptibility testing.
- This culture medium is intended as an aid in the diagnosis of infectious diseases; the interpretation of the results must be made considering the patient's clinical history, the origin of the sample and the results of other diagnostic tests.

13 - PRECAUTIONS AND WARNINGS

- This product is a qualitative *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- This product is not classified as dangerous according to current European legislation.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that these products do not contain any transmissible pathogen. Therefore, it is recommended that the ready-to-use tubes be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Be careful when opening screw cap tubes to prevent injury due to breakage of glass.
- Each tube is for single use only; do not transfer or subdivide the tube content in other containers.
- Muller Kauffmann Tetrathionate Broth Base is sterilized by autoclaving and the tubes are added with the supplements under aseptic conditions; the tubes cannot be considered a "sterile product", but a product with controlled bio-contamination, within the limits of the defined specifications reported on the Quality Control Certificate.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and the tubes inoculated with samples or microbial strains in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

14 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store tubes in their original pack at 2-8°C away from direct light. If properly stored, the tubes may be used up to the expiration date. Do not use the tubes beyond this date. Tubes from opened secondary packages can be used up to the expiration date.















Opened tubes must be used immediately. Before use, check the closing and the integrity of the screw cap. Do not use tubes with signs of deterioration (e.g. microbial contamination, atypical colour).

15 – REFERENCES

1. Muller, L. (1923) C.R. Soc. Biol. (Paris) **89**, 434-443
2. Kauffmann, F. (1935) Z.f. Hyg. **117**, 26-32
3. Rapporto ISTISAN 05/27. ISSN 1127-3117. Infezioni da Salmonella: diagnostica, epidemiologia e sorveglianza. Raccolta a cura di C.Graziani, P.Galetta, L.Busani, AM Dionisi, E.Filetici, A.Ricci, A.Caprioli, I.Luzzi.
4. Rapporto ISTISAN 96/35. ISSN 1123-3117. Metodi di analisi per il controllo microbiologico degli alimenti. Raccolta a cura di D. De Medici, L. Fenicia, L. Orefice e A. Stacchini.
5. MacFaddin JF. Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria. Baltimore: Williams & Wilkins; 1985.

TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	IVD <i>In vitro</i> Diagnostic Medical Device	 Manufacturer	 Do not reuse	 Recyclable pack  This side up
 Temperature limitation	 Content sufficient for <n> tests	 Consult Instructions for Use	 Use by	 Keep away from direct light	 Fragile

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 1	Updated layout and content in compliance with IVDR 2017/746	2021/05

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

