





### 11 - 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.<sup>10</sup>

CONTROL STRAINS	INCUBATION T° / T / ATM	EXPECTED RESULTS
S.Typhimurium ATCC 14028	33-37° / 18-24H / A	good growth after subculture on Mac Conkey Agar
S.flexneri ATCC 12022	33-37° / 18-24H / A	good growth after subculture on Mac Conkey Agar
E.coli ATCC 25922	33-37° / 6-8 H / A	partial or complete inhibition after subculture on Mac Conkey Agar

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

### 12 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of ready-to-use tubes of GN Broth Hajna and of the raw material used for the ready-to-use tube production (dehydrated GN Broth Hajna REF 401524) is 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, 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 ( $G_{TB}$ ). Productivity is tested with the following target strains: S.Typhimurium ATCC 14028, S.Enteritidis NCTC 5188, S.flexneri ATCC 12022, S.sonnei ATCC 9290, S.boydii ATCC 9207. The productivity index  $G_{RB}/G_{TB}$  for each test strain shall be  $\leq 1$ .

Selectivity is evaluated with dilution to extinction method, by inoculating 1 mL of appropriate decimal dilutions of non-target organisms in test tubes, 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 ( $G_{TB}$ ). Selectivity is tested with the following non-target strains: E.coli ATCC 25922, P.vulgaris ATCC 9484 (6-8 hours of incubation), E.faecalis ATCC 19433 e S.aureus ATCC 25923 (18-24 hours of incubation). The selectivity index  $G_{RB}/G_{TB}$  for each test strain shall be  $\geq 1$ .

### 13 - LIMITATIONS OF THE METHOD

- Since heavy growth of some saprophytes (non-pathogens) may exhibit growth on extended incubation, 6-8 hours is the recommended time period for initial subculturing.<sup>2</sup>
- GN Broth Hajna is not the optimal growth medium for *Shigella dysenteriae*.
- Enteric pathogens isolation techniques should include a variety of enrichment broths and isolation media.
- After the enrichment in GN Broth Hajna, 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](http://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.
- Each tube is for single use only; do not transfer or subdivide the tube content in other containers.
- Be careful when opening screw cap tubes to prevent injury due to breakage of glass.
- Ready-to-use tubes of GN Broth Hajna are subject to terminal sterilization by autoclaving.
- 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](http://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. After opening the box, the tubes can be used up to the expiration date. Opened tubes must be used immediately. Before use, check the integrity of the screw cap. Do not use tubes with signs of deterioration (e.g. microbial contamination, atypical colour, precipitate).

### 15 - REFERENCES

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4. Taylor WI, Schelhart D. Isolation of shigellae. V. Comparison of enrichment broths with stools. App Microbiol 1968; 16:1383-1386
5. Taylor WI, Schelhart D. Isolation of shigellae. IV. Comparison of plating media with stools. Amer J Clin Pathol 1967; 48:356-362.





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7. Bonadonna L, Ottaviani M. Rapporti ISTISAN 07/5 Metodi analitici di riferimento per le acque destinate al consumo umano ai sensi del DL.vo 31/2001. Metodi microbiologici. ISS, 2007.
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9. Buchan BW et al. *Escherichia, Shigella and Salmonella*. In Carrol KC, Pfaller MA et al. editors. Manual of clinical microbiology, 12th ed. Washington, DC: American Society for Microbiology; 2019.
10. CLSI (formerly NCCLS) Quality Control of Commercially Prepared Culture Media. Approved Standard, 3rd edition. M22 A3 vol. 24 n° 19, 2004

**TABLE OF APPLICABLE SYMBOLS**

<b>REF</b> or <b>REF</b> Catalogue number	<b>LOT</b> Batch code	<b>IVD</b> <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	2021/04

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

