

ENGLISH

Liquillizer® Instructions for Use

REF P-7510-001-IG and P-7510-002-IG

Intended Use

MetaSystems Liquillizer® is a ready-to-use mucolytic agent. The buffer contains a mucolytic agent for liquefying respiratory samples.

Summary

Liquillizer is intended for the liquefaction of viscous respiratory specimens such as sputa, tracheal secretions, bronchial secretions or bronchoalveolar lavage. The mucolytic Dithiothreitol (DTT)-free buffer reduces specimen viscosity for easier sample handling. The buffer is stable for 4 weeks after opening.

Precautions

- Observe approved biohazard precautions and aseptic techniques. To be used by adequately trained and qualified personnel only.
- All specimens and materials used for processing should be considered as potentially infectious and handled with care to prevent infection of laboratory personnel. Consider all waste including specimens, containers and media as biohazard and dispose of accordingly.
- Instructions should be read and followed carefully.

Storage

This product is ready to use. The sealed bottle can be stored at room temperature until expiration date. Improper storage will result in loss of efficacy. Do not use after expiration date, which appears on package and bottle.

Table 1: Storage conditions of the buffer

| Name | Volume | Store at | Expiration date |
|-------------|--------|------------|---|
| Liquillizer | 125 ml | 15 – 25 °C | unopened see label after opening 4 weeks |
| Liquillizer | 250 ml | 15 – 25 °C | unopened see label after opening 4 weeks |

Product Deterioration

Do not use Liquillizer if: (1) the product shows visible marks of damage or contamination; (2) there is evidence of leakage; (3) the expiration date has passed; (4) there are signs of deterioration.

Material Supplied

| REF No. | Volume | Product description |
|---------------|--------|--------------------------------------|
| P-7510-001-IG | 125 ml | Aqueous solution containing reagents |
| P-7510-002-IG | 250 ml | Aqueous solution containing reagents |

Material Required but not Supplied

Consult laboratory reference manuals for recommended materials and protocols for culture and identification techniques.

Operating Instructions

- For optimal liquefaction transfer an aliquot of the clinical sample into an empty tube and mix sample with an equal volume of Liquillizer or add an equal volume of Liquillizer directly to the sample.
- Vortex and/or shake vigorously until the sample is sufficiently liquefied.

Limitations

- Wear gloves and other protective gear following universal precautions when handling clinical specimens.
- Condition, timing and volume of specimens collected for culture are significant variables in obtaining reliable culture results. Proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms. For specific guidance regarding specimen collection procedures, consult published reference manuals.
- Viability testing with MetaSystems' Liquillizer for cultures was conducted using laboratory strains spiked into sterile water.

Safety Notes

- Not suitable for any other application than intended use.
- The use of this product in association with any diagnostic assay or with any diagnostic instrumentation should be validated before use.
- Do not use if the product is visibly damaged.
- Do not swallow.
- Instructions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized and unqualified use of the product.
- To be used by adequately trained and qualified personnel only.
- It must be assumed that all specimens contain infectious microorganisms; therefore, all specimens must be handled with appropriate precautions.
- For single use only, reuse may cause a risk of infection and inaccurate results.

Waste Disposal

Unused Liquillizer may be considered as non-hazardous waste and disposed of accordingly.

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

Viability Study

A study on survival of respiratory pathogens in contrived specimens that have been stored for 6 hours at room temperature following homogenization with MetaSystems' Liquillizer showed that organisms remained viable and culturable as shown below.

Test Results









| Strains | Cell count CFUs 0h | | Cell count CFUs 6h | |
|--|--------------------|-------------|--------------------|-------------|
| | ddH ₂ O | Liquillizer | ddH ₂ O | Liquillizer |
| <i>Candida albicans</i> (ATCC 90029) | 1 | 2 | 3 | 2 |
| <i>Moraxella catarrhalis</i> (ATCC 25238) | 105 | 108 | 66 | 60 |
| <i>Pseudomonas aeruginosa</i> (ATCC 10145) | 110 | 106 | 72 | 76 |
| <i>Staphylococcus aureus</i> (ATCC 9144) | 57 | 62 | 49 | 33 |
| <i>Streptococcus pneumoniae</i> (ATCC 6303) | 12 | 16 | 2 | 5 |
| <i>Streptococcus pyogenes</i> (ATCC 12344) | 95 | 92 | 71 | 60 |

Procedure of Testing

- Fresh cultures of the test organism were prepared as a 0.5 McFarland in sterile water
- Dilutions were prepared in sterile water starting with the 0.5 McFarland inoculum to obtain a final dilution of 10⁴ CFU/ml
- 50 µl of the final dilution was mixed with 50 µl of sterile water
- 100 µl of mixture was streaked on appropriate culture plates

- 50 µl of the final dilution was mixed with 50 µl of MetaSystems' Liquillizer
- 100 µl of mixture was spread on appropriate culture plates
- Plates were incubated at 37 °C for 24 hours in order to obtain 0h count plates
- 50 µl of the final dilution was mixed with 50 µl of sterile water and kept for 6 hours at room temperature (15 - 25 °C)
- After 6 hours, 100 µl of the mixture was spread on appropriate culture plates
- 50 µl of the final dilution was mixed with 50 µl of MetaSystems' Liquillizer and kept for 6 hours at room temperature (15 - 25 °C)
- After 6 hours, 100 µl of mixture was spread on appropriate culture plates
- Plates were incubated at 37 °C for 24 hours in order to obtain 6h time count plates

Explanation of Symbols and Abbreviations

| | |
|---|---|
|  | Product code / Catalog number |
|  | Lot number |
|  | Use by date |
|  | Temperature limitation for storage |
|  | Manufacturer |
|  | Consult instructions for use |
|  | Protect from direct sun light |
|  | <i>In-vitro</i> diagnostic medical device |
| Hazard symbols | See material safety data sheet (MSDS) |



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