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MAST® SELECTAVIAL

SV40 – Sputagest

Introduction

MAST® Sputagest liquefying agent permits easy and effective isolation of pathogenic organisms of clinical significance responsible for chronic lung disease from sputum or mucosal samples. The effective isolation of bacterial and fungal species is essential for routine clinical laboratory purposes and further diagnoses.
MAST® Sputagest is supplied as individual freeze-dried pellets in glass vials allowing the end-user to prepare a solution of MAST® Sputagest conveniently when required. Each vial is prepared to a 100 mL volume, with 10 vials per pack, enabling the end user to prepare up to one litre of the supplement.

Intended Use

MAST® Sputagest is intended for use as a liquefying agent for human sputum samples prior to microbiological examination. When reconstituted in accordance with the instructions for use it produces a liquid supplement capable of liquefying sputum and mucosal samples, without adversely affecting viability of any microorganisms present in the specimen.

MAST® Sputagest is intended to be used in conjunction with other *in vitro* diagnostic tests to aid the detection and diagnosis of bacterial and fungal pathogens from sputum samples. It is a non-automated, qualitative device, intended to be used by professional trained clinical laboratory users.

FOR *IN VITRO* DIAGNOSTIC USE ONLY

Principle of the test

Sputum samples are often viscous in nature and it can be difficult to isolate pathogenic microorganisms directly from untreated samples. MAST® Sputagest is designed to liquefy sputum samples permitting the isolation of pathogenic microorganisms. The isolation of microorganisms is essential for further identification and diagnoses, treated and liquefied sputum can be inoculated directly onto culture media or examined with other *in vitro* devices.
Once reconstituted a single vial can only be used to make one solution of MAST® Sputagest, which must be used immediately and cannot be stored for future use once reconstituted.

Components

MAST® Sputagest is supplied as 10 glass vials, within a white cardboard box. Each glass vial contains a single white freeze-dried pellet for reconstitution.

Table 1. Formulation of SV40*

Material	Concentration per 100 mL (prepared)
Dithiothreitol (DTT)	0.10 g
Sodium chloride	0.78 g
Potassium chloride	0.02 g
Disodium hydrogen phosphate	0.11 g
Potassium dihydrogen phosphate	0.02 g

*Formulation is subject to minor changes to meet performance criteria
The product is manufactured within an ISO:9001 and ISO:13485 environment. Inter-batch variation is expected to be minimal with no direct impact on the product.

Stability and storage

The expiry date applies to unopened containers of MAST® Sputagest when stored in accordance with the manufacturer's instructions. The expiry date and batch number are indicated on each pack label.

- Store packs at 2 to 8°C
- Use only until expiry date shown on pack label.
- Once reconstituted use immediately.

Warnings and precautions

1. Refer to product Safety Data Sheet before using.
2. To be used only by adequately trained and qualified laboratory personnel. For *in vitro* diagnostic use only.
3. All microbiological cultures, specimens, and equipment used to transfer and manipulate them should be treated as infectious. Autoclave sterilise all biohazard waste before disposal in accordance with local regulations.
4. When handling the product, ensure that local and regulatory health and safety advice is followed.
5. On receipt, store the product at the recommended storage temperature and conditions stated on the pack.
6. Check for signs of deterioration before use. If deterioration is identified, do not use.

MAST® Sputagest is supplied in a sealed primary container, with a rubber stopper and foil lined cap to prevent moisture ingress from the environment.

Materials required but not provided

Standard microbiological supplies and equipment such as bottles, tubes, receptacles, centrifuge, laminar flow cabinet, water bath, pipettes, pipette tips, thermometer, timer, and sterile water.

Procedure

1. Reconstitute the contents of one vial using diluent as specified on the pack label. Aseptically add the diluent directly to the vial using a sterile needle and syringe; draw the diluent into the syringe and after removing the foil lined cap, inject through the rubber stopper of the vial.
2. Mix gently to dissolve completely.

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3. Aseptically, using a fresh needle and syringe, add the vial contents to 95 mL of sterile deionised water. The reconstituted product is now ready to use.

General use

1. Sputum samples may be washed initially with saline.
2. To the sputum sample add an equal volume of reconstituted MAST® Sputagest, shake to mix and incubate in a 36±2 °C water bath.
3. Periodically shake until the liquefaction is complete.
4. Inoculate onto a suitable culture medium to grow any organisms present.

   Prolonged standing will not inhibit floral multiplication

For specific sample processing procedures, refer to local guidelines e.g UKHSA, UK Standards for Microbiology Investigations

Refer to local Health and Safety handling procedures for infectious waste disposal guidelines.

Interpretation of results

After mixing the sample with MAST® Sputagest and following the appropriate incubation, the viscosity of the sample should be reduced. The sample can then be cultured directly only the appropriate medium for further testing.

Limitations of use

MAST® Sputagest is not intended to be used as the sole identification or isolation method for clinical samples in instances where a failure to detect a pathogenic infection would result in death, serious illness or possible transmission of infectious disease.

Quality control

Observe the freeze-dried pellet for deterioration. The pellet is white to off-white in colour and should be examined before use by the user. The reconstituted solution should be clear and colourless with no particulates. If deterioration is identified do not use.

Analytical Performance

Results for select lung pathogens only.
Performance has been evaluated by comparative analysis ($n = 8$) between controlled samples of certified reference organisms supplemented with, and without, MAST® Sputagest.
Performance is quantitatively assessed to determine the Productivity Ratio (P_R) using the following formula;
$P_R = N_S/N_O$
Where
N_S is the total colony count of the test medium
N_O is the total colony count on the reference medium

A P_R of ≥0.7 demonstrates that MAST® Sputagest has had no impact on the organism recovery.

Table 2; the average productivity ratio demonstrated across 8 reference organisms, supplemented with and without Sputagest.

Average P_R	1.00125

References

Bibliography is available on request.

Note:- In accordance with EU Regulation 2017/746 users must report serious incident to the National Competent Authority of all affected countries.