



NOA ANTIMICROBIAL SUPPLEMENT

For *in vitro* diagnostic use only

Contents: 5 vials Code: 5/250



1 INTENDED USE

Biotec's NOA Antimicrobial Supplement is intended for use with the *FASTPlaque-Response*TM test to inhibit the growth of contaminating bacterial and fungal organisms commonly found in respiratory specimens.

2 SUMMARY AND TEST PRINCIPLE

Methods used for the decontamination of sputum for diagnostic testing for tuberculosis may, in some cases, be ineffective in inhibiting the growth of certain contaminating organisms. This may lead to uninterpretable results due to overgrowth of organisms surviving decontamination. Contamination of sputum specimens may affect conventional culture-based methods as well as the phage-based *FASTPlaque-Response* test which is used for the rapid determination of rifampicin resistance directly from sputum specimens.

The NOA Antimicrobial Supplement has been developed for use with the *FASTPlaque-Response* test. Clinical evaluations have found that the combination of aztreonam, oxacillin and nystatin inhibits a range of commonly encountered contaminating organisms found in respiratory specimens, whilst not interfering with the performance of the *FASTPlaque-Response* test.

3 PRODUCT CONTENTS

Reagents provided

Each box contains 5 vials of freeze-dried NOA Antimicrobial Supplement, and each vial is sufficient to supplement 200ml of *Response Medium Plus*.

| Active components | Final concentration (per litre) |
|-------------------|---------------------------------|
| Aztreonam | 30mg |
| Oxacillin | 2mg |
| Nystatin | 50,000IU |

Items required but not provided

NOA Antimicrobial Supplement is intended for use in conjunction with *FASTPlaque-Response* test (Biotec Product code 5/200). No additional materials are required to supplement the *Response Medium Plus*, other than those specified in the *FASTPlaque-Response* instructions for use.

4 PROCEDURE

1. Add 3ml *Response Medium Plus* to reconstitute each vial of antimicrobial. Mix gently to ensure that the reagent is completely dissolved.
2. Add 1ml of the reconstituted antimicrobial to every 100ml of *Response Medium Plus* (i.e. 2ml into 200ml *Response Medium Plus*).
3. Use *Response Medium Plus* supplemented with NOA throughout the *FASTPlaque-Response* procedure for washing of decontaminated sputum samples, in overnight resuscitation, for the reconstitution of *FASTPlaque-Response* reagents (Actiphage, Sensor cells, rifampicin), preparation of controls and Virusol neutralization

5 STORAGE AND SHELF-LIFE

The un-opened vials must be stored at 2-8°C, and used before the expiry date indicated on the label.

Reconstituted NOA Antimicrobial Supplement, and *FASTPlaque-Response* reagents (*Response Medium Plus*, Actiphage, Sensor cells and rifampicin) prepared with the NOA Antimicrobial Supplement must be stored at 2-8°C and used within 7 days of reconstitution.

6 PRECAUTIONS

- NOA Antimicrobial Supplement is intended to be used in conjunction with the *FASTPlaque-Response* test. All warnings and precautions stipulated in the *FASTPlaque-Response* test instructions for use should be followed.
- NOA Antimicrobial Supplement is for *in vitro* diagnostic testing only and should only be handled by experienced laboratory personnel.
- Failure to use the antimicrobial throughout the *FASTPlaque-Response* test procedure may affect the ability of the antimicrobial to control contamination. *FASTPlaque-Response* assay performance may be lost if the antimicrobial supplement is modified, not stored under recommended conditions as detailed above, or not used according to the stated procedure.
- Employ aseptic techniques throughout the use of the antimicrobial supplement.
- Re-use of reagents can introduce laboratory contaminants.
- NOA Antimicrobial Supplement contains a penicillin antibiotic, which may be allergenic to certain individuals.
- NOA Antimicrobial Supplement must be discarded with other biological waste according to local guidelines.

7 PERFORMANCE

The NOA Antimicrobial supplement is effective in controlling the growth of contamination on *FASTPlaque-Response* plates. Use of the NOA Antimicrobial Supplement results in fewer un-interpretable results (due to contamination) for the *FASTPlaque-Response* test.

The use of the NOA Antimicrobial supplement does not affect the *FASTPlaque-Response* tests ability to detect TB, nor the test's ability to determine resistance/ susceptibility to rifampicin.

8 LIMITATIONS

- The NOA Antimicrobial supplement has only been assessed for use with the *FASTPlaque-Response* test. Use of the supplement with the *FASTPlaque-TB* to detect smear negative disease, has not been fully assessed.
- The NOA Antimicrobial supplement may not inhibit all contaminants.
- The use of the NOA Antimicrobial Supplement does not eliminate the need for aseptic technique nor decontamination.

9 REFERENCES

FASTPlaque-Response Instructions for Use. Biotec Laboratories Ltd. Version 2005/09/13.

10 MATERIAL SAFETY DATA SHEET

A material safety data sheet is available from the manufacturer upon request.

11 OTHER INFORMATION

The following symbols have been used on this product:

