

G & M Procter Ltd. Certificate of Analysis

PRODUCT PO0779A ISO-SENSITEST AGAR (4MM DEPTH) 1 PACK OF 10 PLATES

LOT NUMBER	1220269
EXPIRY DATE	2012.08.17
PRODUCTION DATE	2012.06.15
TEST DATE	2012.06.16
REPORTING DATE	2012.06.21

Physical Characteristics	Results	Specification	Accredited Method Reference
Appearance	Straw 2	Straw 2	Appearance and colour
pH (25°C)	7.5	7.2 - 7.6	pH
Fill Volume/Weight	25.8g	25.5 - 26.5g	Fill volume weight check
Sterility @ $22^{\circ}C \& 32^{\circ}C \pm 2^{\circ}C$ for 5 days	Conforms	Within acceptable limits	Ster. at 22,32,37 & 44°C
The sterility test is performed in accordance with	ISO 2859-1: 1999,	AQL 1%, general inspection 1	evel =1.

MICROBIOLOGICAL PERFORMANCE

Each organism must achieve a zone size within the range stated in the range specification.

Target Organism	Zone size (mm)	Zone size range (mm)	Accredited Method Reference	
Zone diameter(mr S.aureus ATCC®9144 Erythromycin 5	n) BSAC 29	22 - 31	Zone Diameter (mm)	
S.aureus ATCC®9144 Gentamicin 10	27	24 - 30	Zone Diameter (mm)	
S.aureus ATCC®9144 Penicillin 1	39	32 - 40	Zone Diameter (mm)	
S.aureus ATCC®9144 Rifampicin 2	35	27 - 39	Zone Diameter (mm)	

All of the results reported within the G & M Procter Certificate of Analysis relate only to the sample tested. The results were derived from a representative sample of the batch and were obtained at the time of release. All test specifications are defined in the G&M Procter manufacturing and test procedures for this product, which are available on request. The uncertainty of measurement introduced during pH, fill weight and microbiological performance testing has been determined. Values are not reported on the Certificate of Analysis but details can be provided on request.



Jan Snanball

Ian Snowball Product Performance Manager G & M Procter Ltd.

Performance tested by the Quality Control Laboratory, G & M Procter Ltd, 4 Auld Bond Road, Perth, PH1 3FX, a UKAS accredited testing laboratory NO. 2727



G & M Procter Ltd. Certificate of Analysis

Target Organism	Zone size (mm)	Zone size range (mm)	Accredited Method Reference
Zone diameter(mm S.aureus ATCC®9144 Teicoplanin 30	n) BSAC 20	17 - 23	Zone Diameter (mm)
S.aureus ATCC®9144 Vancomycin 5	16	14 - 20	Zone Diameter (mm)
E.coli ATCC®10536 Ampicillin 10	21	21 - 26	Zone Diameter (mm)
E.coli ATCC®10536 Ceftazidime 30	40	32 - 40	Zone Diameter (mm)
E.coli ATCC®10536 Trimethoprim 2.5	30	30 - 37	Zone Diameter (mm)
E.coli ATCC®10536 Cefuroxime 30	29	25 - 32	Zone Diameter (mm)
E.coli ATCC®10536 Ciprofloxacin 1	39	31 - 40	Zone Diameter (mm)
E.coli ATCC®10536 Gentamicin 10	27	21 - 27	Zone Diameter (mm)
E.faecalis ATCC®29212 Ampicillin 10	30	26 - 35	Zone Diameter (mm)
E.faecalis ATCC®29212 Gentamicin 200	27	22 - 27	Zone Diameter (mm)

All of the results reported within the G & M Procter Certificate of Analysis relate only to the sample tested. The results were derived from a representative sample of the batch and were obtained at the time of release. All test specifications are defined in the G&M Procter manufacturing and test procedures for this product, which are available on request. The uncertainty of measurement introduced during pH, fill weight and microbiological performance testing has been determined. Values are not reported on the Certificate of Analysis but details can be provided on request.



Jan Snowball

Ian Snowball Product Performance Manager G & M Procter Ltd.



G & M Procter Ltd. Certificate of Analysis

Target Organism	Zone size (mm)	Zone size range (mm)	Accredited Method Reference
Zone diameter(mr E.faecalis ATCC®29212 Teicoplanin 30	n) BSAC 23	19 - 25	Zone Diameter (mm)
E.faecalis ATCC®29212 Vancomycin 5	15	13 - 19	Zone Diameter (mm)
P.aeruginosa ATCC®27853 Amikacin 30	30	26 - 32	Zone Diameter (mm)
P.aeruginosa ATCC®27853 Ceftazidime 30	34	27 - 35	Zone Diameter (mm)
P.aeruginosa ATCC®27853 Ciprofloxacin 1	28	24 - 30	Zone Diameter (mm)
P.aeruginosa ATCC®27853 Colistin 25	19	16 - 20	Zone Diameter (mm)
P.aeruginosa ATCC®27853 Gentamicin 10	27	22 - 28	Zone Diameter (mm)
P.aeruginosa ATCC®27853 Imipenem 10	26	23 - 28	Zone Diameter (mm)

All of the results reported within the G & M Procter Certificate of Analysis relate only to the sample tested. The results were derived from a representative sample of the batch and were obtained at the time of release. All test specifications are defined in the G&M Procter manufacturing and test procedures for this product, which are available on request. The uncertainty of measurement introduced during pH, fill weight and microbiological performance testing has been determined. Values are not reported on the Certificate of Analysis but details can be provided on request.

2727

Jan Snowball

Ian Snowball Product Performance Manager G & M Procter Ltd.



CERTIFICATE OF ANALYSIS

Delivery/Customer information

Date Printed 2013.11.08 Delivery No.

Customer

Customer Order number

The information given is believed to be correct. However both the information and the product are offered without warranty for any specific application other than that specified. The results reported were derived from a representative sample of the batch and were obtained at the time of release.

Jan Snanboll

Ian Snowball Product Performance Manager, G&M Procter Ltd

Our management system is certified by BSI as being in conformity with ISO 9001:2008, certificate number FM 27644 and ISO 13485:2003, certificate number MD 85850.

G & M Procter Ltd, Thermo Fisher Scientific, Microbiology, 4 Auld Bond Road, Perth, PH1 3FX