

CERTIFICATE OF ANALYSIS

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PRODUCT PP2027

HEKTOEN/XLD

LOT NUMBER 1260694

EXPIRY DATE 2013.08.12

RELEASE DATE 2013.06.05

Physical Testing Side 1 Results Specification Tested in accordance with Oxoid Method QC13 unless otherwise stated				
Appearance (Colour)	Pass	Green		
Clarity	Pass	Translucent		
Gel Strength	Pass	Satisfactory		
рН	7.7	7.3 - 7.7		
Microbiological Testing Side 1	Result	Specification	Method	
Escherichia coli ATCC® 25922	Pass	No growth	QC27	
Salmonella typhimurium ATCC® 14028	Pass	Clear cols/black centres	QC27	
Shigella flexneri ATCC® 12022	Pass	Clear colonies	QC27	
Enterococcus faecalis ATCC® 29212	Pass	No growth	QC27	
Physical Testing Side 2	Results	Specification		
Tested in accordance with Oxoid Method QC1	3 unless otherwise	stated		
Appearance (Colour)	Pass	Orange/pink		
Clarity	Pass	Translucent		
Gel Strength	Pass	Satisfactory		
pH	7.6	7.2 - 7.6		
Microbiological Testing Side 2	Result	Specification	Method	
Escherichia coli ATCC® 25922	Pass	No growth	QC27	
Salmonella typhimurium ATCC® 14028	Pass	Clear cols/black centres	QC27	
Shigella flexneri ATCC® 12022	Pass	Clear colonies	QC27	
Enterococcus faecalis ATCC® 29212	Pass	No growth	QC27	



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20 Dalgleish Street, Thebarton, South Australia 5031 Tel: Toll Free 1 800 33 11 63, Fax Toll free 1 800 007 054

Email: micro_orders@thermofisher.com Website: www.thermofisher.com.au



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Sterility Testing Results Specification

Tested in accordance with Oxoid Method QC13 unless otherwise stated

Sterility @ 30°C for 3 days /sample plan Pass Within Limits

This test is performed in accordance Oxoid method QC21, NATA FADs, ASM Guidelines: Normal inspection AQL 2.5,

General inspection level=1

The results reported were obtained at the time of release. Products microbiologically tested are inoculated with bacterial suspension containing either greater or equal to 10,000 cfu for non-target organisms or less than or equal to 100 cfu for target organisms.

Results are recorded semi-quantitatively in comparsion to an appropriate control medium. A pass for a target organism is 80-100% recovery (4-5+ growth). A pass for a non-target organism is less than 20% recovery (inhibited, less than 1+ growth).

This product is stable to the stated expiry date when stored in accordance with instructions as per product label.

Released by: Rina Pattullo

MANUFACTURED AND TESTED BY: Thermo Fisher Scientific, Microbiology Division

20 Dalgleish Street, Thebarton, South Australia 5031 Tel: Toll Free 1 800 33 11 63, Fax Toll free 1 800 007 054 Email: micro_orders@thermofisher.com Website: www.thermofisher.com.au