

Certificate of Analysis

Client

E&O Laboratories Ltd
Burnhouse
Bonnybridge
Scotland
FK4 2HH



E&O Laboratories Ltd

Sample: BM8300 - Non-acidified Pyruvate LJ Med
Batch Number: 04088675
Expiry Date: 2021-08-07
Date Received: 2020-11-11
Date Tested: 2020-11-11
Sample Condition: Satisfactory
Sample Number: 390375

Burnhouse, Bonnybridge
Scotland, FK4 2HH
Telephone: 01324 840404
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Email: info@eolabs.com

Accredited Test Method: See table below

Productivity	Result	Colonial Appearance	Colonial Appearance Specification
Mycobacterium intracellulare NCTC 10682	Growth	2+ / 3+ Growth within 3-4 weeks	2+ / 3+ Growth within 3-4 weeks
Mycobacterium fortuitum NCTC 10394	Growth	2+ / 3+ Growth within 3-4 weeks	2+ / 3+ Growth within 3-4 weeks
Mycobacterium kansasii NCTC 13024	Growth	2+ / 3+ Growth within 3-4 weeks	2+ / 3+ Growth within 3-4 weeks
Mycobacterium bovis NCTC 5692	Growth	2+ / 3+ Growth within 3-4 weeks	2+ / 3+ Growth within 3-4 weeks
Mycobacterium tuberculosis ATCC 35818	Growth	2+ / 3+ Growth within 3-4 weeks	2+ / 3+ Growth within 3-4 weeks

For solid media the RGI is a calculation of the % growth on the test media compared with the growth on a control media. The test medium must achieve an RGI between 70-120% for non-selective media / $\geq 50\%$ for selective media. For liquid media growth is determined from a subculture of the test broth inoculated with 10 - 100 cfu of the target organism.

Physical	Result	Specifications	Accredited Test Method
Sterility	Conforms	Within acceptable limits	ED/SOP/005 Visual check and growth assessment following incubation for 3 days at 15-25°C and 37°C
Sterility sampling is performed in accordance with ISO 2859-1:1999*. The inspection level is $\geq 0.4\%$ of the batch and the reject level ≤ 7 units depending on batch size.			
pH	N/A	N/A	ED/SOP/003 measurement by pH meter
Colour	Conforms	256-6 - 282-7 Pale Green	ED/SOP/009 by visual observation. Range measured using Pantone® 4 colour process guide

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Fill Quantity	Conforms	9ml +/- 0.3	ED/SOP/054 by gravimetric determination
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Accredited Test Method for Solid Media	Accredited Test Method for Liquid Media	Accredited Test Method for Diluents
ED/SOP/008 Quantitative evaluation using spread inoculum technique	ED/SOP/008 Semi quantitative inoculation with growth assessment from subculture	ED/SOP/008 Semi quantitative evaluation of viability maintenance after a holding time of 45 minutes

All of the results on this certificate of analysis relate only to the samples submitted.

Test specifications are based on ISO 11133:2014/Amd/:2020 and internal product specifications

*Sterility sampling is outwith scope of accreditation.



Douglas Cameron
Technical Manager, E&O Laboratories Ltd