

Certificate of Analysis

Client

E&O Laboratories Ltd
Burnhouse
Bonnybridge
Scotland
FK4 2HH



E&O Laboratories Ltd

Sample: BM0432 - Tryptone Soya Broth (USP)
Batch Number: 04090325
Expiry Date: 2022-01-25
Date Received: 2021-01-26
Date Tested: 2021-01-26
Sample Condition: Satisfactory
Sample Number: 395593

Burnhouse, Bonnybridge
Scotland, FK4 2HH
Telephone: 01324 840404
Fax: 01324 841314
Email: info@eolabs.com

Accredited Test Method: See table below

Productivity	Result	Colonial Appearance	Colonial Appearance Specification
Escherichia coli ATCC 8739	Growth	Good growth in broth. Grey colonies	Good growth in broth. Grey colonies
Aspergillus brasiliensis ATCC 16404	Growth	Good growth in broth. White colonies. Reverse side is pale yellow.	Good growth in broth. White colonies. Reverse side is pale yellow.
Candida albicans ATCC 10231	Growth	Good growth in broth. White colonies.	Good growth in broth. White colonies.
Pseudomonas aeruginosa ATCC 9027	Growth	Good growth in broth. Green / grey pigmented colonies.	Good growth in broth. Green / grey pigmented colonies.
Bacillus subtilis ATCC 6633	Growth	Good growth in broth. Cream colonies.	Good growth in broth. Cream colonies.
Staphylococcus aureus ATCC 6538	Growth	Good growth in broth. White colonies.	Good growth in broth. White colonies.

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.

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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	7.3	7.3 +/- 0.2	ED/SOP/003 measurement by pH meter
Colour	Conforms	5-8 - 6-8 Straw	ED/SOP/009 by visual observation. Range measured using Pantone® 4 colour process guide
Fill Quantity	Conforms	100ml +/- 0.3	ED/SOP/054 by gravimetric determination

Accredited Test Method for Solid Media

ED/SOP/008 Quantitative evaluation using spread inoculum technique

Accredited Test Method for Liquid Media

ED/SOP/008 Semi quantitative inoculation with growth assessment from subculture

Accredited Test Method for Diluents

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