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Product Stability & Validation Report

Stability Study of BR0055B - Anaerobic Indicator

DOMINIQUE DUTSCHER SAS

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BR0055B – Anaerobic Indicator
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Executive Summary

The purpose of this report is to record the stability data of BR0055B, Anaerobic Indicator.

It is a requirement that the stability of this product is validated, and the physical adequacy of the shelf life is demonstrated.

This report shows the stability validation of BR0055B, Anaerobic Indicator throughout the shelf life of 2 years under real time stability test conditions stored throughout the shelf life at 8°C. This verifies performance when the product is stored at the recommended temperature range of 2°C - 8°C.

The performance of the product was within the required specifications at all time points tested throughout the 2 year shelf life of the product.

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1. Introduction

The purpose of this report is to record the stability validation of BR0055B, Anaerobic Indicator when stored at the recommended storage conditions 2°C - 8°C.

The stability data has been generated in accordance with the pre-established protocol and is based on data from real-time testing. Testing of the product at specified time intervals was chosen to encompass the target shelf life of 2 years and continued testing for a further 4 to 6 months to monitor for significant degradation in performance of the product.

2. Method

The following summarises the key events of the BR0055B, Anaerobic Indicator stability testing.

The stability testing follows the guideline outlined by BS EN 23640:2015 'Evaluation of stability of in vitro diagnostic reagents' and was conducted in accordance with Work Instruction BT-WI-0172.

Three batches were tested to validate the shelf life of BR0055B, Anaerobic Indicator from the Thermo Fisher Scientific Microbiology Division manufacturing plant in Basingstoke.

Lot number: 1805138	**Expiry: 31/05/2020**
Lot number: 2007138	**Expiry: 31/07/2022**
Lot number: 2107138	**Expiry: 01/07/2023**

The Quality Control testing of the BR at point of manufacture is used as a baseline test. These batches underwent a simulated transportation cycle prior to being stored for stability testing.

1805138 T_0 = 0 years (baseline), T_1 = 0.6 years, T_2 = 1.0 year, T_3 = 1.5 year T_4 = 2.0 year and T_5 = 2.5 years.

2007138 T_0 = 0 years (baseline), T_1 = 1.0 year (50%), T_2 = 2.0 years (100%), and T_3 = 2.5 years (120%).

2007138 T_0 = 0 years (baseline), T_1 = 0.9 years (50%), T_2 = 2.0 years (100%), and T_3 = 2.3 years (120%).

T_0 = 0 year (baseline) test was conducted by Quality Control following manufacture.

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2.1 Transportation Cycle

Samples were received into the Thermo Fisher Scientific Basingstoke Microbiology Laboratory. All of the samples were put through temperature fluctuations designed to mimic transportation. The temperature fluctuations are outlined below:

- 35°C for 7 days, followed by;
- 30°C for 1 day, followed by;
- 25°C for 2 days, followed by;
- 35°C for 1 day.

Once the temperature fluctuations had been completed, the samples were divided and stored at the specified temperatures.

2.2 Acceptance Criteria

Table 1 Acceptable Physical Characteristics

Acceptable criteria	
Organism	**Specification; appearance**
Colour during incubation in gas jar	Colourless
Colour after incubation in gas jar	Pink
Colour in anaerobic cabinet	Colourless

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3. Results

3.11 Lot Number 1805138

Table 2 Physical Characteristics

Acceptable criteria		Storage conditions (°C)	Time tested (years / date)											
			0	12/06/2018	0.6	18/01/2019	1.0	26/06/2019	1.5	26/11/2019	2.0	05/06/2020	2.5	03/12/2020
Organism	Specification; appearance		Appearance	Appearance Typical: (Yes/No)	Appearance	Appearance Typical: (Yes/No)	Appearance	Appearance Typical: (Yes/No)	Appearance	Appearance Typical: (Yes/No)	Appearance	Appearance Typical: (Yes/No)	Appearance	Appearance Typical: (Yes/No)
Colour during incubation in gas jar	Colourless	2 (transp.)	Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y	NT	NT	NT	NT
		2			Colourless	Y	Colourless	Y	Colourless	Y	NT	NT	NT	NT
		8 (transp.)			Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y
		8			Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y
Colour after incubation in gas jar	Pink	2 (transp.)	Pink	Y	Pink	Y	Pink	Y	Pink	Y	NT	NT	NT	NT
		2			Pink	Y	Pink	Y	Pink	Y	NT	NT	NT	NT
		8 (transp.)			Pink	Y	Pink	Y	Pink	Y	Pink	Y	Pink	Y
		8			Pink	Y	Pink	Y	Pink	Y	Pink	Y	Pink	Y
Colour in anaerobic cabinet	Colourless	2 (transp.)	Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y	NT	NT	NT	NT
		2			Colourless	Y	Colourless	Y	Colourless	Y	NT	NT	NT	NT
		8 (transp.)			Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y
		8			Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y

NT = Not Tested see discussion

3.12 Lot Number 2007138

Table 3 Physical Characteristics

Acceptable criteria		Storage conditions (°C)	Time tested (years / date)							
			0	03/08/2020	50%	14/07/2021	100%	01/08/2022	120%	09/01/2023
Organism	Specification; appearance		Appearance	Appearance Typical: (Yes/No)	Appearance	Appearance Typical: (Yes/No)	Appearance	Appearance Typical: (Yes/No)	Appearance	Appearance Typical: (Yes/No)
Colour during incubation in gas jar	Colourless	8 (transp.)	Colourless	Yes	Colourless	Yes	Colourless	Yes	Colourless	Colourless
Colour after incubation in gas jar	Pink	8 (transp.)	Pink	Yes	Pink	Yes	Pink	Yes	Pink	Pink
Colour in anaerobic cabinet	Colourless	8 (transp.)	Colourless	Yes	Colourless	Yes	Colourless	Yes	Colourless	Colourless

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3.13 Lot Number 2107138

Table 4 Physical Characteristics

Acceptable criteria		Time tested (months / date)							
		0	23/08/2021	0.9	03/08/2022	2	14/08/2023	2.3	14/12/2023
Condition	Specification; appearance	Appearance	Appearance Typical: (Yes/No)	Appearance	Appearance Typical: (Yes/No)	Appearance	Appearance Typical: (Yes/No)	Appearance	Appearance Typical: (Yes/No)
Colour during incubation in gas jar	Colourless	Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y
Colour after incubation in gas jar	Pink	Pink	Y	Pink	Y	Pink	Y	Pink	Y
Colour in anaerobic cabinet	Colourless	Colourless	Y	Colourless	Y	Colourless	Y	Colourless	Y

3.2 Results Summary

Table 5 Results Summary

Characteristic	Result
Physical Characteristics	PASS
Overall Product Pass/Fail?	PASS

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4. Discussion

The physical performance of BR0055B, Anaerobic Indicator lot numbers, 1805138, 2007138, and 2107138 were satisfactory in meeting with the acceptance criteria set for the full shelf life of 2 years.

The performance of the product was within the required specifications at all time points tested throughout the 2 year shelf life of the product.

For lot number 1805138, expiry and post expiry testing was only conducted on samples stored at 8°C in accordance with updated stability test procedures. This is worst case recommended storage and so is deemed satisfactory in confirming stability of the product.

For lot numbers 2007138 and 2107138, 50%, 100% and 120% tests were done in accordance with these updated stability testing procedures and so these batches were only tested at the worst-case recommended storage of 8˚C.

5. Conclusion

The stability tests performed confirmed the shelf-life adequacy of all three batches of the product BR0055B, Anaerobic Indicator.

The stability is therefore satisfactory, and the physical adequacy reached.

The BR0055B, Anaerobic Indicator has met the acceptance criteria for its stated shelf life of 2 years and the storage temperature of 2°C - 8°C.

The ability of the product to withstand temperature fluctuations designed to simulate transportation has also been demonstrated.

6. Report History

Version No.	Month/Year	Author	Reason for Change
01	Dec 2020	C.Todd	Initial Report
02	Jan 2023	M.Read	Additional Batch
03	June 2024	D. Chilvers	Additional Batch

7. Stability Non-Conformance

Issue	Time point seen	Deviation Ref.	Decision
N/A	N/A	N/A	N/A

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