

CERTIFICATE OF CONFORMITY

Name of Product: MICROGEN Campylobacter kit
 Product Code: M46
 Components: One of each:- M46a, M46b, M46c, M46d

1. All components in this kit comply with current Microgen Bioproducts approved specifications.
2. Performance complies with current release specifications.

KEY DATA SUMMARY

Component	Part Number	Lot	Expiry	Lot, expiry correct SOP 340	Component PMP reviewed SOP 337
Test Latex reagent	M46a	23201	2023-02	PASS	PASS
Control latex reagent	M46b	21101	2023-02	PASS	PASS
Positive control	M46c	20001	2022-09	PASS	PASS
Sample diluent	M46d	17805	2023-01	PASS	PASS
Assembly	M46	18413	2022-09	PASS	PASS
Overall Expiry Date:		2022-09			

SIGNATURE: *Danehl*

DATE: 22/Apr/21

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Name of Product: MICROGEN Campylobacter
 Product Code: M46
 Components: One of each:- M46a, M46b, M46c, M46d, Slide

Batch: 18413

1	M46a Test Latex Reagent APPEARANCE CAP COLOUR FILL VOLUME SODIUM AZIDE SENSITIVITY TO STANDARD CAMPYLOBACTER Standard Neat 1:4 1:16 IMMUNOGLOBULIN LOADING	Smooth milky suspension Blue 2.75 ± 0.25ml Positive +++ + or more ± or - End point within one doubling dilution of control latex	Complies Complies Complies Complies Complies Complies Complies Complies
2	M46b Control Latex Reagent APPEARANCE CAP COLOUR FILL VOLUME SODIUM AZIDE SENSITIVITY TO STANDARD CAMPYLOBACTER IMMUNOGLOBULIN LOADING	Smooth milky suspension Yellow 2.75 ± 0.25ml Positive Non reactive End point within one doubling dilution of test latex	Complies Complies Complies Complies Complies Complies
3	M46c Positive Control APPEARANCE CAP COLOUR FILL VOLUME SODIUM AZIDE REACTIVITY	Colourless/ slightly turbid suspension Black 1.15 ± 0.15ml Positive Demonstrates acceptable agglutination patterns against test latex (M46a). Non reactive against control latex (M46b)	Complies Complies Complies Complies Complies
4	M46d Sample diluent APPEARANCE CAP COLOUR FILL VOLUME SODIUM AZIDE REACTIVITY	Clear colourless solution White 5.15±0.15mL Positive Non reactive with both test latex and control latex	Complies Complies Complies Complies Complies

Page 4 to be attached to complete this certificate

Date: 22/Apr/21

Signed: *Dana H*