



**MICROGEN BIOPRODUCTS**  
**CERTIFICATE OF CONFORMITY**

Name of Product: MICROSCREEN 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	17201	2019-04	PASS	PASS
Control latex reagent	M46b	17501	2019-04	PASS	PASS
Positive control	M46c	15801	2018-10	PASS	PASS
Sample diluent	M46d	14302	2019-02	PASS	PASS
Assembly	M46	14971	2018-10	PASS	PASS
Overall Expiry Date:		2018-10			

SIGNATURE: 

DATE: 28 / Apr / 2017



# MICROGEN BIOPRODUCTS

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

Batch:

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: 28/07/2014 Signed: