

MICROGEN BIOPRODUCTS
CERTIFICATE OF CONFORMITY

Name of Product:	Aspergillus Kit
Product Code:	FSK1 CE
Components:	Aspergillus fumigatus antigens, matched positive and negative controls

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

RESULTS

1. Fill volume	FSK1a 2.5 - 3.0ml	Complies
	FSK1b 4.0 - 5.0ml	Complies
	FSK1c-f 0.5 - 0.6ml	Complies
2. Azide identity	Present in all reagents	Complies
3. Function	All antigens authenticated by an independent consultant. Positive control - gives precipitin line(s) with all antigens on double diffusion plate. Negative control - gives no precipitin lines with all kit antigens on double diffusion plates.	Complies

KEY DATA SUMMARY

Component	Part Number	Lot	Expiry	Lot, expiry correct SOP 340	Component PMP reviewed SOP 337
Negative control	FSKa	37901	2021-01	PASS	PASS
Positive control	FSK1b	As a	As a	PASS	PASS
20mg/ml CF	FSK1c	As a	As a	PASS	PASS
2mg/ml CF	FSK1d	As a	As a	PASS	PASS
20mg/ml SOM	FSK1e	As a	As a	PASS	PASS
2mg/ml SOM	FSK1f	As a	As a	PASS	PASS
Assembly	FSK1	37901	2021-01	PASS	PASS

Overall Expiry Date:

2021-01

SIGNATURE:

Danna Li

DATE:

28/Jan/20