

MICROGEN BIOPRODUCTS

CERTIFICATE OF CONFORMITY

Name of Product: MICROGEN Staph
 Product Code: M43(CE)
 Components: One of each:- M43a, M43b

1. All components in this kit comply with current Microgen Bioproducts approved specifications.
2. Performance of kit complies with current release specifications.
3. Performance of test latex with QC panel gives expected pattern of reactions and complies with current release specifications.

S. aureus (MRSA) MBCC15, positive
 Staph aureus MBCC193, positive
 Staph aureus MBCC194, positive
 Staph aureus MBCC195, positive
 Staph aureus MBCC197, positive
 S. aureus (MRSA) MBCC568, positive
 Staph aureus MBCC693, positive

Staph epid. MBCC198, negative
 Staph epid. MBCC199, negative
 Saline, negative

4. All components containing human product have been tested for HIV 1/2 Ab, HCV and HbsAg as individual donors and were found to be negative.

KEY DATA SUMMARY

Component	Part Number	Lot	D.O.M	Expiry	Lot, expiry correct SOP 340	Component PMP reviewed SOP 337
Latex reagent	M43a	17601	2021-05	2023-05	PASS	PASS
Positive Control	M43b	20701	2021-05	2022-11	PASS	PASS
Assembly	M43	15011	2021-06	2022-11	PASS	PASS
Overall Expiry Date:	2022-11					

SIGNATURE: *Diana Li*

DATE: 16/June/24