

MICROGEN BIOPRODUCTS

CERTIFICATE OF CONFORMITY

Name of Product:	Infectious Mononucleosis Kit
Product Code:	M121 CE Marked
Components:	One of each:- M121a, M121b, M121c, M121d, slide, Instructions for Use

1. All components in this kit comply with current Microgen Bioproducts approved specifications.
2. Performance complies with current release specifications.
3. 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
Guinea pig antigen	M121a CE	14801	2019-05	2020-10	PASS	PASS
Ox cell antigen	M121b CE	27201	2019-05	2020-11	PASS	PASS
Horse cell reagent	M121c CE	20201	2019-04	2019-11	PASS	PASS
Positive control	M121d CE	15601	2019-05	2020-11	PASS	PASS
Assembly	M121 CE	23991	2019-05	2019-11	PASS	PASS
Overall Expiry Date:		2019-11				

SIGNATURE: Sajana
DATE: 14 Jun 19

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Batch: 23991

1.	M121a Guinea pig antigen	APPEARANCE CAP COLOUR FILL VOLUME FUNCTION	Pale brown suspension Yellow $2.25 \pm 0.25\text{ml}$ Complies with specification	Complies Complies Complies Complies
2.	M121b Ox cell antigen	APPEARANCE CAP COLOUR FILL VOLUME FUNCTION	Brown suspension White $2.25 \pm 0.25\text{ml}$ Complies with specification	Complies Complies Complies Complies
3.	M121c Horse cell reagent	APPEARANCE CAP COLOUR FILL VOLUME FUNCTION	Dark brown/red suspension Blue $4.30 \pm 0.30\text{ml}$ Complies with specification	Complies Complies Complies Complies
4.	M121d Positive control	APPEARANCE CAP COLOUR FILL VOLUME FUNCTION	Colourless liquid Black $2.25 \pm 0.25\text{ml}$ Complies with specification	Complies Complies Complies Complies

Page 3 to be attached to complete this certificate

Date: 14 Jun 19

Signed: *Sajana*