

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	13701	2018-02	2019-12	PASS	PASS
Ox cell antigen	M121b CE	25901	2018-02	2019-08	PASS	PASS
Horse cell reagent	M121c CE	19101	2018-01	2018-08	PASS	PASS
Positive control	M121d CE	14501	2018-02	2019-08	PASS	PASS
Assembly	M121 CE	22681		2018-08	PASS	PASS

Overall Expiry Date: 2018-08

SIGNATURE: *Sajana*
 DATE: 23 Feb 2018

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Batch:

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

Page 3 to be attached to complete this certificate

Date: 23 Feb 18

Signed: *Sajana*