



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	12201	2016-04	2017-02	PASS	PASS
Ox cell antigen	M121b CE	24001	2016-04	2017-06	PASS	PASS
Horse cell reagent	M121c CE	17601	2016-03	2016-10	PASS	PASS
Positive control	M121d CE	13001	2016-04	2017-10	PASS	PASS
Assembly	M121 CE	20961	2016-04	2016-10	PASS	PASS
Overall Expiry Date:	2016-10					

SIGNATURE:

DATE:

26 Apr 2016