



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 | 13001 | 2017-03 | 2018-03 | PASS | PASS |
| Ox cell antigen | M121b CE | 25101 | 2017-03 | 2018-08 | PASS | PASS |
| Horse cell reagent | M121c CE | 18401 | 2017-03 | 2017-09 | PASS | PASS |
| Positive control | M121d CE | 13801 | 2017-03 | 2018-03 | PASS | PASS |
| Assembly | M121 CE | 21771 | 2017-03 | 2017-09 | PASS | PASS |

| | |
|----------------------|---------|
| Overall Expiry Date: | 2017-09 |
|----------------------|---------|

| | |
|------------|------------------------|
| SIGNATURE: | <i>RAL</i> |
| DATE: | <i>07 / Apr / 2017</i> |



MICROGEN BIOPRODUCTS

CERTIFICATE OF CONFORMITY

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

Batch:

| | | | | |
|----|--------------------------|---|---|--|
| 1. | M121a Guinea pig antigen | APPEARANCE CAP COLOUR FILL VOLUME FUNCTION | Pale brown suspension Yellow 2.25 ± 0.25ml Complies with specification | Complies Complies Complies Complies |
| 2. | M121b Ox cell antigen | APPEARANCE CAP COLOUR FILL VOLUME FUNCTION | Brown suspension White 2.25 ± 0.25ml 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 ± 0.30ml Complies with specification | Complies Complies Complies Complies |
| 4. | M121d Positive control | APPEARANCE CAP COLOUR FILL VOLUME FUNCTION | Colourless liquid Black 2.25 ± 0.25ml Complies with specification | Complies Complies Complies Complies |

Page 3 to be attached to complete this certificate

Date: 07/01/2017 Signed: 