

# Medical Device Alert

Ref: MDA/2011/104 Issued: 03 November 2011 at 14:30

## Device

Laboratory based syphilis test.

Mercia Syphilis M kit  
manufactured by Microgen  
Bioproducts Limited.

Lots 052X1, 053X1 and 05411A.  
Product code: M404.



## Problem

Higher level of non-specific cross-reactivity leading to false positive syphilis IgM results observed with lot numbers 052X1, 053X1 and 05411A.

This may lead to misdiagnosis of early acute infection.

## Action by

Reference laboratories.  
Directors of pathology.  
Biomedical scientists (microbiologists).

## Action

- Do not use affected lots.
- Routine diagnostic microbiology laboratories and confirmatory laboratories that have used the affected lots should consider the need to review previous positive results.
- Laboratories undertaking confirmatory testing should consider informing referring laboratories of your review where relevant.
- Laboratories that have received results from confirmatory laboratories should examine the reporting comments. If there are any positive IgM-only results, repeat samples must be requested for these.
- Contact your confirmatory laboratory or the HPA Sexually Transmitted Bacteria Reference Laboratory (STBRL) for advice on a suitable approach to risk assessment.

## CAS deadlines

Action underway: 10 November 2011

Action complete: 05 December 2011

## Contact

### Manufacturer

Christopher Rackham  
Microgen Bioproducts Ltd

Tel: 01276 600 081

Fax: 01276 600 151

Email: [crackham@microgenbioproducts.com](mailto:crackham@microgenbioproducts.com)

## Device

Mercia Syphilis M is an IgM antibody class capture immunosorbent assay for the detection of *Treponema pallidum*-specific IgM in human serum, which in combination with *T. pallidum* IgG assays can be used in differential diagnosis between past and active syphilis infection. This notice does not apply to the Mikrogen recomWell IgM assay.

## Action

Additionally, the Health Protection Agency (HPA) incident response group advises that:

- syphilis IgM positive results should be tested by at least one additional treponemal test (EIA/TPPA) and a non-treponemal test (RPR/VDRL)
- results of syphilis IgM tests used in isolation should be interpreted with caution and correlated with other test parameters and the likelihood of infection.

## Problem

Microgen Bioproducts issued two Field Safety Notices (see appendix) warning that product performance studies with a primary reference panel of sera indicated that the three lots of Mercia Syphilis M kits (lots 052X1, 053X1 and 05411A) exhibit a higher than expected level of false positive results.

These three lots were on sale from 19 October 2010 to 3 October 2011 inclusive.

The investigation into the root cause of this issue is ongoing.

## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

#### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Antenatal screening coordinators
- Biomedical science departments
- Clinical pathologists
- Clinical pathology directors
- Directors of genitourinary medicine clinics
- Genitourinary outpatient clinics
- GUM physicians
- Infectious disease wards
- Medical directors
- Microbiologists
- Purchasing managers
- Risk managers
- Special care baby units
- Supplies managers

### **Health Protection Agency**

Directors for onward distribution to:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of health, safety and quality
- Health protection nurses
- HPA laboratories
- Laboratory managers
- Regional directors
- Regional microbiologists
- Risk manager
- Safety officers

### **Primary care trusts**

CAS liaison officers for onward distribution to all relevant staff including:

- Directors of public health
- General practitioners
- Health visitors
- Immunisation co-ordinators
- Infection control nurses
- Practice managers

### **Independent distribution**

#### **Establishments registered with the Care Quality Commission (CQC) (England only)**

This alert should be read by:

- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## **Contacts**

### **Manufacturer**

Christopher R Rackham  
Operations Director  
Microgen Bioproducts Ltd  
1 Admiralty Way  
Camberley GU15 3DT  
Tel: 01276 600 081  
Fax: 01276 600 151  
Email: [crackham@microgenbioproducts.com](mailto:crackham@microgenbioproducts.com)

## **England**

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/104** or **2011/009/001/081/006**

### **Technical aspects**

Mojisola Ajeneye or Rosalind Polley  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7271 / 7119  
Fax: 020 8754 3965  
Email: [mojisola.ajeneye@mhra.gsi.gov.uk](mailto:mojisola.ajeneye@mhra.gsi.gov.uk)  
[rosalind.polley@mhra.gsi.gov.uk](mailto:rosalind.polley@mhra.gsi.gov.uk)

**Clinical aspects**

Dr Nicola Lennard  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7126  
Fax: 020 8754 3965  
Email: [nicola.lennard@mhra.gsi.gov.uk](mailto:nicola.lennard@mhra.gsi.gov.uk)

**Health Protection Agency Contact**

Dr Colin Brown  
HPA Centre for Infections  
The Sexually Transmitted Bacteria Reference Laboratory (STBRL)  
61 Colindale Avenue  
London NW9 5HT  
Tel: 020 8327 7563  
Email: [colin.brown@hpa.org.uk](mailto:colin.brown@hpa.org.uk)

**How to report adverse incidents**

Please report via our website <http://www.mhra.gov.uk>  
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

**Northern Ireland**

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.  
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre  
Health Estates Investment Group  
Room 17  
Annex 6  
Castle Buildings  
Stormont Estate  
Dundonald BT4 3SQ  
Tel: 02890 523 704  
Fax: 02890 523 900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)  
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

**How to report adverse incidents in Northern Ireland**

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>  
Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre  
Health Facilities Scotland  
NHS National Services Scotland  
Gyle Square  
1 South Gyle Crescent  
Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes  
Senior Medical Officer  
Medical Device Alerts  
Welsh Assembly Government  
Cathays Park  
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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Addressees may take copies for distribution within their own organisations

## Appendix

### MICROGEN BIOPRODUCTS LIMITED

1 Admiralty Way  
Camberley  
Surrey GU15 3DT  
United Kingdom

Telephone: +44 (0)1276 600 081  
Fax: +44 (0)1276 600 151



Name and Address

28 October 2011

#### **Urgent – Field Safety Notice:**

**Subject: Mercia Syphilis M; Product Code M404CE Lot 05411A**

Dear

We have identified a problem with Syphilis M kit Lot 05411A which exhibits a lower specificity than normal, meaning there is an increased risk of false positive Syphilis IgM results.

This Safety Notice supplements the one sent on 24<sup>th</sup> August 2011 but relates to a lot number that we had previously excluded from that notice.

Our advice is that:

- 1) Lot 05411A should not be used.
- 2) Positive results obtained with this lot should be confirmed by an alternative method if possible.
- 3) Laboratories should consider the need to review IgM positive only results obtained with this lot

Please confirm receipt of this communication and indicate the number of kits remaining in your inventory by faxing back or e mailing page 2 of this communication. We will provide credit or replacement product for these.

Microgen (or where appropriate your Microgen distributor) will be contacting you shortly to discuss the future supply of Syphilis M kits. We have an alternative Syphilis IgM Capture kit available, which has been independently developed and is manufactured by our parent company Lab 21.

Please accept our apologies again for this situation which we are working hard to resolve.

Yours sincerely

Christopher R Rackham

Website: [www.microgenbioproducts.com](http://www.microgenbioproducts.com)

Registered in England number 2832020

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Operations Director

Customer Name  
Address

To: C Rackham, Microgen Bioproducts  
FAX: 01276 600151  
E mail: crackham@microgenbioproducts.com

I confirm receipt of Microgen Product Safety Notice dated 28 October 2011.

The number of Mercia Syphilis M kits we have remaining in inventory are:

Lot 05441A .....

Signed ..... Date .....

Website: [www.microgenbioproducts.com](http://www.microgenbioproducts.com)

Registered in England number 2832020

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MICROGEN BIOPRODUCTS LIMITED

1 Admiralty Way  
Camberley  
Surrey GU15 3DT  
United Kingdom

Telephone: +44 (0)1276 600 081  
Fax: +44 (0)1276 600 151



Customer Name  
Address

24 August 2011

Dear

**Urgent - Product Safety Notice:  
Product Code M404 Mercia Syphilis M kit lots 052X1 and 053X1**

We have received one report from a user of lot 053X1 Mercia Syphilis M (Product code M404) of false positive Syphilis IgM results.

Further product performance studies with a primary reference panel of sera indicates that the two lots of Mercia Syphilis M kits (Lots 052X1, and 053X1) exhibit a higher level of false positive results than normal. These two lots have been on sale from 19 October 2010 to 25 May 2011 but the report of false positive reactions has only recently been received and investigated. A later lot (05411A) does not exhibit this problem.

Given this situation we would specifically draw your attention to the precautionary statements in section 11 of the Instructions For Use as follows:

- Diagnosis of an infectious disease should not be established on the basis of a single test result. A precise diagnosis, in fact, should take into consideration clinical history, symptomatology, as well as serological data. Serological data, however, have restricted value in immunosuppressed patients.
- To estimate (primary or recurrent) *T.pallidum* infections by serology it is advised to test serum pairs. The second serum of a pair can be drawn 14-21 days after the first serum is obtained. Each serum pair should be tested on the same day and in the same test run to allow interpretation of significant antibody level differences. It is advised to perform a combination of IgM and IgG testing.
- In a clinical evaluation this *Treponema pallidum* IgM EIA showed reactivity with some of the following interfering sera: ANA-IgM, Epstein Barr Virus IgM, Borrelia IgM and Parvo-B19 IgM.

Our further advice is as follows:

1. Please confirm receipt of this communication and detail the number of kits remaining in your inventory of these two lots by faxing or e mailing back page 2 of this letter.
2. Do not use remaining kits from these lots in your inventory. Any positive results should be confirmed by an alternative method. Microgen will replace these kits free of charge as soon as we have manufactured a new lot (estimate 2- 3 weeks).

Website: [www.microgenbioproducts.com](http://www.microgenbioproducts.com)

Registered in England number 2832020



Please accept our apologies for this situation. The quality of our products is of paramount importance to us and we are working hard to make sufficient replacement material available to you as soon as possible.

Yours sincerely

Christopher R Rackham  
Operations Director

.....  
Customer Name  
Address

**To:** Customer Services, Microgen Bioproducts  
**FAX:** 01276 600151  
**E mail:** customerservices@microgenbioproducts.com

I confirm receipt of Microgen Product Safety Notice dated 24 August 2011.

The number of Mercia Syphilis M kits we have remaining in inventory are:

Lot 052X1 .....

Lot 053X1 .....

Signed ..... Date .....

Website: [www.microgenbioproducts.com](http://www.microgenbioproducts.com)

Registered in England number 2832020

