

Medical Device Alert

Ref: MDA/2013/012 Issued: 19 March 2013 at 11:00

Device

Diagnostic test strips and cassettes for urinalysis, pregnancy testing, menopause testing and opiates testing, manufactured by:

- IND Diagnostics Inc, Canada
- Alere International Ltd
- Barrier Healthcare Ltd
- E-Pharm Ltd

Problem

Health Canada (the Canadian regulatory authority for medical devices) has suspended sale of these kits in Canada due to concerns about the manufacturer's quality systems – see:
<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/23151a-eng.php>

Action

Users should report any incidents of false results involving these products to the MHRA and the supplier, to enable the MHRA to monitor the situation in the UK.

Note: the MHRA will consider the need to issue further advice based upon information received from UK users.

Action by

Healthcare personnel treating patients based on results from test strips.

Healthcare personnel using, supplying, supervising, quality assuring or distributing these test strips.

CAS deadlines

Action underway: 26 March 2013

Action complete: 19 April 2013

Note: These deadlines are for systems to be in place to take actions.

Contact

Authorised Representative

Mr Bernard Tremaine
 MD&QA Services Ltd

Tel: 0161 870 6751

Fax: 0161 903 9787

Email: info@mdqa.co.uk

Device

The table below lists test strips that have been supplied in the UK between January 2011 and March 2013

Manufacturer	Device Type	Device Name
IND Diagnostics	Urinalysis Reagent Test Strips	Urinalysis Reagent Test Strips
IND Diagnostics	HCG Pregnancy Test	Indicator One-Step Urine Pregnancy Test (Cassette Format)
		Indicator One-Step Urine Pregnancy Test (Ministrip Format)
		Indicator One-Step Home Pregnancy Test (Midstream Format)
		Indicator One-Step Home Pregnancy Test (Mini-Midstream Format)
IND Diagnostics	FSH Menopause tests	One Step FSH Menopause Test (Strip Format)
		One Step FSH Menopause Test (Cassette Format)
		One Step FSH Menopause Test (Midstream Format)
IND Diagnostics	Opiates Test	IND One Step Opiates Test
Alere International Ltd.	HCG Pregnancy test	Axis Shield Pregnancy test dipstick and cassette
Barrier Healthcare Ltd.	Urinalysis Reagent Test Strips	DIA-CHECK Urinalysis Reagent Strips
E-Pharm	HCG Pregnancy Test	PREGTEST (Strip format)
		PREGTEST (Cassette format)
		PREGTEST (Midstream format)

Problem

Health Canada's decision to suspend these licences is not based on an identified issue with the safety and effectiveness of any particular device.

The MHRA has not received any reports of adverse incidents in the UK involving these devices.

The product is currently still available for use in the UK

The MHRA is continuing to monitor this situation.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- 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)

- OFSTED (Directors of Children's Services) for information
- Health and Safety Executive
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

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:

- All departments
- All staff
- All wards
- Biochemists
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Medical directors
- Nursing executive directors
- Theatres
- Wheelchair service managers

Primary care trusts

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

- Community children's nurses
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Community pharmacists
- District nurses
- General dental practitioners
- General practitioners
- Health visitors
- Minor injury units
- NHS walk-in centres
- Practice managers
- Practice nurses
- Walk-in centres

Independent distribution

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

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Clinics
- Hospices
- 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 and requesting this facility.

Contacts

Manufacturers

IND Diagnostic Inc.
1629 Fosters Way,
Delta,
B.C. V3M 6S7,
Canada.
Fax: +1 604 522 6331
Email: Info@ind.ca

Alere International Ltd,
Vulcan House,
Parkmore,
East Business Park Ballybrit,
Ireland.
Tel: 01382 422300

Barrier Healthcare Ltd.
Britania Mill,
Upton Road,
Kexby,
Lincs,
DN21 5NF.
Tel: 01427787828
Fax:01427787848

E-Pharm Ltd,
Aqua House,
24, Valley Walk,
Croydon.
CR0 8SR.
Tel: 0794 119 7095

Distributors

Ambe Ltd,
Ambe House,
Commerce Way,
Edenbridge,
Kent,
TN8 6ED.
Tel: 01732 760900

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Home Health UK Ltd,
Unit 11, Peerglow Industrial Estate,
Olds Approach,
Watford,
Hertfordshire,
WD18 9SR.
Tel: 01923 711 511
Fax: 01923 711 550

Rosevale
22 Calow Brook Drive Industrial Estate
Hasland
Chesterfield
S41 0DR
UK
Tel: 07857 300260

Authorised UK Representative

Medical Device & QA Services Ltd.
Altrincham,
WA15 7SN.
Tel: +44 161 870 6751
Fax: +44 161 903 9787
Email: info@mdqa.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/012** or **2013/002/004/291/024**

Technical aspects

Bina Mackenzie or Susan Mclellan,
Medicines & Healthcare products Regulatory Agency,
Floor 4 – Devices,
151 Buckingham Palace Road,
London, SW1W 9SZ.
Tel: 020 3080 7229/7215 Fax: 020 8754 3965
Email: bina.mackenzie@mhra.gsi.gov.uk
susan.mclellan@mhra.gsi.gov.uk

Clinical aspects

Dr Nicola Lennard,
Medicines & Healthcare products Regulatory Agency,
Floor 4 – Devices,
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London, SW1W 9SZ.
Tel: 020 3080 7126 Fax: 020 8754 3965
Email: nicola.lennard@mhra.gsi.gov.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

<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

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

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate

Welsh Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk