# 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](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.

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

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)
Issued: 19 March 2013 at 11:00

Ref: MDA/2013/012

- 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
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,
151 Buckingham Palace Road,
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](http://www.mhra.gov.uk)

Further information about CAS can be found at [https://www.cas.dh.gov.uk/Home.aspx](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](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](http://www.dhsspsni.gov.uk/niaic)

Further information about SABS can be found at [http://sabs.dhsspsni.gov.uk/](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.iric@nhs.net  

### 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