

# Medical Device Alert

## Immediate action

Ref: MDA/2011/014 Issued: 14 February 2011 at 11:30

### Device

HLA (human leukocyte antigen) tissue typing kits.  
 RELI SSO HLA-B, DRB, DQB1 and DRB1 manufactured by Invitrogen.

All lots manufactured since 2004.



Problem	Action
<p>Potential for false positive results that may cause incorrect typing or inaccurate cross-matching results.</p>	<p>Establish a plan to review and confirm all previous typing results obtained solely using this product.</p> <p>When using HLA-B, DRB and DQB1:</p> <ul style="list-style-type: none"> <li>• Confirm typing results using a different technique.</li> <li>• Use the updated manual analysis interpretation tables, <a href="#">HLA-B</a>, <a href="#">HLA-DRB</a> and <a href="#">HLA-DQB1</a> and the information in the <a href="#">Field Safety Notices</a>.</li> </ul> <p>Return unused HLA-DRB1 product to the manufacturer and discontinue use as this is failing to meet performance characteristics.</p>
Action by	
<p>HLA typing laboratories.</p>	
CAS deadlines	Contact
<p>Action underway: 21 February 2011</p> <p>Action complete: 07 March 2011</p>	<p><b>Manufacturer</b>            Life Technologies / Invitrogen            Tel: 0141 814 6100            Fax: 0141 814 6258            E-mail: <a href="mailto:tech_support@invitrogen.com">tech_support@invitrogen.com</a></p>

## Problem

Invitrogen has informed us that it was not using the correct final product specification of the manual analysis interpretation tables, which was leading to errors in interpretation of results. Potential additional mismatches may have been hidden and may not have been identified. Furthermore, potentially compatible HLA matches may have been missed on the basis of this misinterpretation.

Pattern matching program (PMP) software has been released which has not been validated for clinical use and should not be used clinically.

## Action

When reviewing patient results, you should bear in mind the following advice from the NHS Blood and Transplant, Histocompatibility & Immunogenetics function:

Haematopoietic stem cell transplantation:

- Review matching of donor recipient pairs and identify any changes in the mismatch status.
- Review donor and recipient typings to determine whether
  - > this could have affected the chance of receiving a suitable transplant or
  - > the outcome of any transplant which took place.

(In addition, the Human Tissue Authority asks to be notified of Serious Adverse Events and Reactions.)

Solid organ transplantation

- Review any cases and correct any mismatch grades that are incorrect. These data should be taken into consideration when:
  - > reviewing post-transplant antibody specificity
  - > determining permissible and non-permissible mismatches for future transplantation in any cases where the transplant has failed or subsequently fails.
- Notify any changes to NHS Blood and Transplant – Directorate of Organ Donation & Transplantation (NHSBT-ODT) so that correct data are used in any survival analysis performed by ODT.

Platelet transfusion

- Review HLA types of donors used to support patients refractory to random platelets.

Where you identify that there may be a problem with any historical results you should inform your clinical transplant units immediately and give an indication of the steps that you are taking to identify any potentially affected patients.

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this Notice. GPs need take no further action on receipt of this Alert.

## Distribution

This MDA has been sent to:

- UK stem cell registries, British Bone Marrow Registry (BBMR), Antony Nolan Trust (ANT), Welsh Bone Marrow Donor Registry (WBMDR)
- NHS Blood and Transplant – Directorate of Organ Donation & Transplantation
- 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 (Chief Executives)
- 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:

- Biomedical science departments
- Bone marrow transplant units
- Cardiac transplant units
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Haematologists
- Histology
- Medical directors
- Pathologists
- Renal medicine departments
- Renal medicine, directors of
- Renal transplant units
- Risk managers
- Tissue typing laboratories
- Transplant coordinators

### **Health Protection Agency**

Directors for onward distribution to:

- Divisional directors
- Risk manager

### **Primary care trusts**

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

- Directors of public health
- General practitioners

### **Independent distribution**

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

- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- 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**

Invitrogen Ltd  
11 Bassendale Road  
Croft Business Park  
Bromborough  
CH62 3QL  
Tel: 0141 814 6100  
Fax: 0141 814 6258  
E-mail: [tech\\_support@invitrogen.com](mailto:tech_support@invitrogen.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/014** or **2010/012/020/291/001**.

### Technical aspects

Rosalind Polley  
Medicines & Healthcare products Regulatory Agency  
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Fax: 020 8754 3965  
Email: [rosalind.polley@mhra.gsi.gov.uk](mailto:rosalind.polley@mhra.gsi.gov.uk)

### Clinical aspects

Jonathan Plumb  
Medicines & Healthcare products Regulatory Agency  
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London SW1W 9SZ  
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### 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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