Medical Device Alert

MDA/2017/033 Issued: 03 October 2017 at 14:00 Valid until: October 2018

Professional use HIV test: Alere HIV Combo – risk of false positive results

Summary

Manufactured by Alere – point-of-care tests for use ONLY in professional clinical settings: specific lots are affected.

Action

- Identify affected devices, which are listed in the manufacturer's Field Safety Notice.
- Where affected devices have been used, ensure that initially reactive p24 antigen and/or antibody results that were obtained from EDTA whole blood samples are retested using another method.
- Ensure the results are evaluated in consideration of the overall clinical evaluation before a diagnosis is made.
- Ensure all relevant members of staff receive the manufacturer’s Field Safety Notice and that they understand the problem and to check that the actions have been taken.

Action by

- Genitourinary medicine (GUM) clinics
- General practitioners
- Pharmacists
- Purchasing managers

Deadlines for actions

Actions underway: 17 October 2017
Actions complete: 14 November 2017
**Manufacturer contacts**

**Manufacturer**

Simon Richards  
Alere Ltd  
Pepper Road  
Hazel Grove  
Stockport  
Cheshire SK7 5BW  

Tel: 07785 387 505  
Email: simon.richards@alere.com

**UK distributors**

United Healthcare Global Medical  
Building 8  
Vantage Point Business Village  
Mitcheldean GL17 0DD

Tel: 01594 545 100  
Email: phil.hughes@unitedhealthcareglobal.com

Kuehne + Nagel Ltd  
LCS Services  
Shropshire TF2 8JT

Tel: 0117 332 8676  
Email: leidos-tvs-med-techcon1b@mod.uk

ANP Pharma Ltd  
55 Hainault Road  
Leytonstone E11 1EA

Tel: 0208 558 8886  
Email: info@anppharma.co.uk

**Distribution**

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

**Trusts (NHS boards in Scotland)**  
CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Biomedical science departments  
- Clinical pathologists  
- Gynaecologists  
- Gynaecology departments  
- Gynaecology nurses  
- Hospital pharmacies  
- Hospital pharmacists
• Infection control departments
• Infection control nurses
• Infection prevention and control directors
• Medical directors
• NHS walk-in centres
• Obstetricians
• Obstetrics and gynaecology departments
• Obstetrics and gynaecology directors
• Obstetrics departments
• Obstetrics nurses
• Point of care testing co-ordinators
• Purchasing managers
• Supplies managers
• Virologists
• Walk-in centres

Public Health England
Directors for onward distribution to:
• Collaborating centres
• Consultants in communicable disease control
• Divisional directors
• Heads of department
• Health protection nurses
• PHE laboratories
• Laboratory managers
• Regional microbiologists
• Risk manager
• Safety officers

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:
• General practice managers
• General practice nurses

Independent distribution
Establishments registered with the Care Quality Commission (CQC) (England only)
• Clinics
• 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 and requesting this facility.
## Enquiries

**England**
Send enquiries about this notice to MHRA, quoting reference number MDA/2017/033 or 2017/007/017/291/028.

**Technical aspects**
Jazmin McCalla-Bedward, MHRA  
Tel: 020 3080 6270  
Email: jazmin.mccalla-bedward@mhra.gov.uk

**Clinical aspects**
Dr Kate Antrobus, MHRA  
Tel: 020 3080 7274  
Email: dct@mhra.gov.uk

### Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

**Northern Ireland**
Alerts in Northern Ireland are distributed via the NICAS system.  
Enquiries and adverse incident reports in Northern Ireland should be addressed to:  
Northern Ireland Adverse Incident Centre, CMO Group,  
Department of Health, Social Services and Public Safety  
Tel: 028 9052 3868  
Email: niaic@health-ni.gov.uk  
https://www.health-ni.gov.uk/niaic

### Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

**Scotland**
Enquiries and adverse incident reports in Scotland should be addressed to:  
Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland  
Tel: 0131 275 7575  
Fax: 0131 314 0722  
Email: nss.iric@nhs.net

### Reporting adverse incidents in Scotland
Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.  
Private facilities providing care to private clients report to the Care Inspectorate and MHRA.
**Wales**

Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government
Tel: 02920 823 624 / 02920 825 510
Email: Haz-Aic@wales.gsi.gov.uk

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**Reporting adverse incidents in Wales**


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