Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2016/004 Issued: 24 March 2016 at 12:00 Valid until: March 2017

Estradiol immunoassays – interference from the drug fulvestrant (Faslodex®) may cause falsely elevated estradiol results.

Summary

Manufactured by Siemens Healthcare Diagnostics Inc. / Siemens Healthcare Diagnostics Ltd and Roche Diagnostics GmbH- assay interference from the drug fulvestrant (Faslodex®) may cause falsely elevated estradiol results.

Both Siemens and Roche have issued field safety notices (FSNs) highlighting this issue. Estradiol assays from other manufacturers may also be affected by fulvestrant (Faslodex®) interference and this is currently under investigation.

Action

Action by Laboratory staff

- Determine if estradiol immunoassays are used in your laboratory.
- Continue to use affected estradiol immunoassays for patients not on fulvestrant.
- If measuring estradiol levels in patients on fulvestrant consider alternative methods, such as Liquid Chromatography-Mass Spectrometry (LC-MS).
- Consider the need to carry out a review of previously reported test results.
- Monitor the MHRA website or subscribe to email alerts for any possible further FSNs on this issue.

Action by Healthcare personnel managing patients on this drug

- When test requests include estradiol, state if the patient is on fulvestrant.
- Consider reassessing the menopausal status of patients on fulvestrant by other means where necessary.

Deadlines for actions

Actions underway: 04 April 2016
Actions complete: 25 April 2016

Department of Health, Social Services and Public Safety www.dhsspsni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

SIEMENS:

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
ADVIA Centaur® Enhanced Estradiol[1]	eE2	10490889 10491445 10697757	10490889 10491445 10697757	All lots
Dimension Vista® LOCI Estradiol[2]	E2	K6463	10489099	All lots
IMMULITE®/ IMMULITE 1000 Estradiol	E2	LKE21 LKE21(D)	10381132 10702832	All lots
IMMULITE® 2000 Estradiol[3]	E2	L2KE22 L2KE22 (D) L2KE26 L2KE26 (D)	10381178 10702833 10381177 10702834	All lots

1 The same reagents are used on the ADVIA Centaur, ADVIA Centaur XP, ADVIA Centaur XPT and ADVIA Centaur CP systems.
2 The same reagents are used on the Dimension Vista 500 and 1500 systems.
3 The same reagents are used on the IMMULITE 2000 and IMMULITE 2000 XPi systems.

ROCHE:

Product Name	Product Description	GMMI / Part No	Lot Number
Estradiol II	Elecsys Estradiol II assay	Estradiol II 03000079190	All lots
Estradiol III	Elecsys Estradiol III assay	Estradiol III 06656021190	All lots

Please note oestradiol is used interchangeably with estradiol.

Problem / background

Siemens and Roche both manufacture a number of estradiol assays and have communicated that the drug fulvestrant (Faslodex®) may cause falsely elevated estradiol results in assays. Fulvestrant has a similar chemical structure to estradiol and may cross-react with the antibodies used in immunoassays.

Fulvestrant is indicated for the treatment of postmenopausal women with oestrogen receptor positive breast cancer, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen.
If the listed estradiol assays are used for this group of post-menopausal women, falsely elevated estradiol results could lead to misinterpretation of the menopausal status of these women. This may result in treatment with fulvestrant being altered.

Manufacturer contacts

ADVIA Centaur ®

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591, USA
Tel: Please see below
Email: Please see below

Dimension Vista ®

Siemens Healthcare Diagnostics Inc.
500 GBC Drive
Newark, DE 19714, USA
Tel: Please see below
E Mail: Please see below

Phone contact for the above USA based manufacturers in the UK (European Authorised Representative)

Siemens Healthcare Diagnostics Limited
Newton House, Sir William Siemens Square
Frimley, Camberley
GU16 8QD
Tel: 01908 282 433
Email: dx-argcm-eu.healthcare@siemens.com

IMMULITE ® / IMMULITE 1000, IMMULITE 2000 ®

Siemens Healthcare Products Limited
Glyn Rhonwy
LLanberis, Caernarfon, Gwynedd, LL55 4EL
Tel: 01286 871 871
E Mail: HDXWalesQualitySystemsVigilance.healthcare@siemens.com

Estradiol II/ Estradiol III

Stefanie Koehler
Roche Diagnostics GmbH
Sandhofer Strasse 116
Mannheim
68305
DE
Tel: +49 621 759-3511
Email: dia.vigilance-eea@roche.com

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

- Adult intensive care units
- All wards
- Biochemists
- Biomedical science departments
- Clinical pathologists
- Clinical pathology directors
- Community hospitals
- Community nurses
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Intensive care nursing staff (adult)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Medical oncologists
- Medical oncology, directors of
- Oncology nurse specialists
- Radiation & medical oncology departments
- Radiation oncologists
- Radiation oncology, directors of
- Risk managers
- Supplies managers

Public Health England
Directors for onward distribution to:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses
- HPA laboratories
- Laboratory managers
- Regional business managers
- Regional directors
- Regional epidemiologists
- Regional leads
- 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
- General practitioners

'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.'

Social services
Liaison officers for onward distribution to all relevant staff including:

Independent distribution

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

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2016/004** or **2016/001/018/601/005**.

Technical aspects
Caroline Olabisi, MHRA
Tel: 020 3080 6580
Email: caroline.olabisi@mhra.gsi.gov.uk

Clinical aspects
Dr Soundararajan Jagdish, MHRA
Tel: 020 3080 7187
Email: s.jagdish@mhra.gsi.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 NI SABS 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 Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

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

NHS Boards and Local Authorities in Scotland – report to Health Facilities 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

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).