Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/023 Issued: 05 July 2018 at 13:00 Valid until: July 2019

Combur[10] Test UX and Chemstrip 10 A test strips – risk of falsely low results when measuring test strips on the Urisys 1100 urine analyser.

Summary

Manufactured by Roche Diagnostics GmbH – Incorrect Limit of Detection (LoD) for protein, nitrite, ketone bodies, leukocytes, blood: intact erythrocytes, which may adversely impact patient treatment.

Action

- Identify affected devices, which are listed in the manufacturer's Field Safety Notice (FSN)
- Ensure all relevant members of staff receive the manufacturer's FSN and that they understand the problem and actions to be taken.
- Follow the manufacturer's workaround until advised otherwise by the manufacturer.
- If any adverse event occurs relating to this issue please report this to MHRA via Yellow Card or the relevant devolved administrations (Scotland, Wales and Northern Ireland).

Action by
Point of Care testing Co-ordinators
Laboratory Managers
Biomedical scientists
Medical and nursing staff
Walk in Centres/Treatment Centres
Pharmacy staff
General Practitioners

Deadlines for actions
Actions underway: 19 July 2018
Actions complete: 02 August 2018

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

In addition to the Field Safety Notice, which details affected product, please refer to the spreadsheet which accompanies this MDA for additional unique device identification information.

Problem / background

The Urisys 1100 urine analyser is a semi-automated analyser, which can be used in both lab or near patient testing settings. It is used to read and evaluate urine test strips Combur[10] Test UX and Chemstrip 10 A.

Due to an incorrect Instruction for Use (IFU) Limit of Detection (LoD) claim for the Combur[10] Test UX and Chemstrip 10 A test strips there is a risk of falsely low results being generated when measuring the following parameters: protein, nitrite, ketone bodies, leukocytes, blood: intact erythrocytes on the Urisys 1100 analyser. This may adversely impact patient treatment.

The visual reading for all parameters are not affected.

The manufacturer has taken action to revise the LoD claims in the device labelling for the affected parameters.

The FSN refers to both Combur[10] Test UX and Chemstrip 10 A test strips. Roche has confirmed that Chemstrip 10 A is not intended for use in the European Market.

Manufacturer contacts

Roche Diagnostics Ltd
Charles Avenue
Burgess Hill
West Sussex RH15 9RY
Registration number: 571546

Technical Support Hotline UK: 08081001920
Email: burgesshill.tsgpm@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 NICAS liaison officers for onward distribution to all relevant staff including:

- A&E departments
- A&E nurses
- Adult intensive care units
- All departments
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthetic nursing staff
- Anti-coagulation clinics
- Biochemists

- Biomedical science departments
- Cardiac laboratory technicians
- Cardiology departments
- Cardiology nurses
- Cardiothoracic departments
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Colposcopy departments
- Community children’s nurses
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Dietetics departments
- District nurses
- Endocrinology units
- ENT departments
- Equipment stores
- Gastroenterology departments
- General surgery
- Gynaecology departments
- Gynaecology nurses
- Haemodialysis nurses
- Haemodialysis units
- Health visitors
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Infection control departments
- Infection control nurses
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- IV nurse specialists
- Minor injury units
- Maternity units
- Microbiologists
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- NHS walk-in centres
- Obstetrics and gynaecology departments
- Obstetrics departments
- Obstetrics nurses
- Oncology nurse specialists

- Operating department practitioners
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric nurse specialists
- Paediatric wards
- Paediatrics departments
- Palliative care teams
- Paramedics
- Peritoneal dialysis units
- Pharmacists
- Point of care testing co-ordinators
- Purchasing managers
- Radiation & medical oncology departments
- Renal medicine departments
- Risk managers
- School nurses
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urology departments
- Virologists
- Walk-in centres

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
- PHE 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:

- Community pharmacists
- Dispensing opticians
- General practitioners
- Nutritional nurse specialists
- Occupational health departments
- General practice managers
- General practice nurses

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Education departments for equipment held in schools
- Environmental health officers
- Equipment stores
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers
- Occupational health departments
- Occupational therapists

Independent distribution

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

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED

- Children's services
- Educational establishments with beds for children
- Residential special schools

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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/023** or **2018/004/020/291/005.**

Technical aspects
Daryl Colombage, MHRA

Tel: 020 3080 6740
Email: daryl.colombage@mhra.gov.uk

Clinical aspects
Devices Clinical Team, 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

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).