Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/015 Issued: 08 June 2020 at 10:00

1 - Laboratory based tests for COVID-19 antibodies – unvalidated sample type
2 - Capillary blood sample collection kits – unvalidated for home use

Summary

Results from laboratory-based tests for COVID-19 antibodies using capillary blood sample collection kits may not be reliable.

Action

Laboratories offering a COVID-19 testing service for the public, private healthcare or NHS:

- Pause the service immediately if your service uses capillary blood samples. Do not process new samples. Before issuing any results for tests already processed, ensure that due consideration has been given to Article 15 of the GDPR and Data Protection Act 2018 Part 2 of Schedule 3.
- Contact all your customers within a week of receiving this alert to notify them that you have paused your service, at the request of MHRA, as the results from this sample type may not be reliable.
- Only use assays with the sample types covered by the CE mark.
- If you are offering the sample kit, you should undertake a usability study and a stability study to prove it can be used safely by the intended user. This is most important for home users. The sample collection kit should be additionally CE marked as an IVD kit.
- Verify that the sample collection kit used by your customer is CE marked and suitable for use by the intended user, your laboratory and with the manufacturer's assay.
- All laboratories offering a COVID-19 testing service should apply to UKAS to include COVID-19 testing in their scope.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by

- Biomedical scientists
- Pathology managers
- Medical directors

Deadlines for actions
Actions underway: 15 June 2020
Actions complete: 13 July 2020

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Problem / background

MHRA is aware that some laboratories are providing COVID-19 testing service whereby the sample type has not been validated or verified by the manufacturer of the assay. This represents off label use and is therefore not covered under the CE mark of the assay.

The test involves collecting a capillary blood sample into a small container following a set of instructions. The container is then sent to a laboratory for analysis and the results are returned direct to the person who took the test or the person's GP or healthcare professional, with an indication of the reliability of the result.

The laboratory tests are CE marked and safe for use on blood drawn from the vein by a healthcare professional but have not yet been validated by the manufacturer of the test to be used with a capillary blood sample. The sample collection kits have not yet been validated for home use. We can't be sure that people collecting samples at home are able to do this in a way that the laboratory can process the sample to give reliable results.

All UKAS accredited laboratories offering a COVID-19 testing service should hold evidence of their sample type validation and verification data.

MHRA has updated our guidance for COVID-19 antibody testing services for industry and members of the public.

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
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Community children's nurses
- Community nurses
- Microbiologists
- NHS walk-in centres
- Outpatient clinics
- Outpatient theatre managers
- Pharmaceutical advisors
- Pharmacists
- Phlebotomists
- Point of care testing co-ordinators
- School nurses
- Virologists
- Walk-in centres

Public Health England

Directors for onward distribution to:

- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Laboratory managers
- PHE laboratories

NHS England area teams

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

- Community pharmacists
- General practice managers
- General practice nurses
- General practitioners (for information only)
- Occupational health departments

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.

Independent distribution

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

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Hospitals in the independent sector
- 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 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/2020/015 or 2020/006/001/210/002.

Technical aspects

Bina Mackenzie, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).