

AN (NI) 2001/02

DATE: 5 February 2001

**For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency**



**HEALTH ESTATES
ESTATE POLICY**

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

**BIOKIT BioELISA SYPHILIS COLOUR TEST
KIT**

MANUFACTURER/SUPPLIER

Biokit Ltd

PROBLEM

Possibility of false negative and false positive results with this test kit.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Device Managers
- Directors and Managers of Pathology and Laboratory Services
- Medical Directors
- Nursing Directors
- Directors of Midwifery
- Microbiologists
- Microbiology Departments
- Clinical Pathologists
- Consultants in Communicable Disease
- Consultants in Genitourinary Medicine
- Antenatal Clinics
- Family Planning Nurses
- Supplies Officers
- Directors of Public Health
- Public Health Laboratory Services
- Independent Healthcare Sector
- General Medical Practitioners
- Community Midwives
- Family Planning Clinics
- Pregnancy Advisory Clinics
- Practice Nurses
- GUM Clinics
- Obstetricians
- Gynaecologists

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

ACTION

Laboratories should suspend use of this test kit until further advice is issued by NIAIC.

Alternative testing should be used in all circumstances.

Report all cases of known incorrect results with these test kits to NIAIC at the address below.

ADVICE

NOTICE

BACKGROUND

The Department has received reports from a number of laboratories regarding incorrect results associated with the use of the Biokit BioELISA syphilis colour EIA test kit.

These reports, which include both false negative and false positive results, are not restricted to a particular batch.

There has been one report of reduced absorbance with internal controls, cut-off controls and high positive controls.

There has been one report of a false negative result that was given to a pregnant patient.

This Advice Notice is being issued as a precautionary measure until the possible causes of the incorrect results are known.

The Department is actively investigating the causes of these incorrect results and will issue further advice when more information is available. In the meantime, laboratories should suspend use of this kit and use alternative testing that covers similar stages of infection as appropriate.

All cases of known incorrect results should be reported to NIAIC. Reports of experience from laboratories using this kit will assist the investigation into the possible causes of the incorrect results.

This product is not used to screen the blood supply.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Michael Hutchinson
Biokit Ltd
Ash House, Ash Road
New Ash Green, Longfield
Kent
DA3 8JD
Tel: 01474 874 426
Fax: 01474 872 388

Enquires to the NIAIC should quote the reference number AN (NI) 2001/02 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Marked for the attention of Mr Brian Godfrey

Tel: 02890 523714
Fax: 02890 523900
Email: brian.godfrey@dhsspsni.gov.uk

Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2001/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided.

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Aisíneacht Feidhmeannach don Roinn Sláinte. Serbhíst Sóisialta agus Sábháilteacht Phoiblí*



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