

AN (NI) 2001/09

DATE: 17 December 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:

LCx Chlamydia trachomatis Assay

MANUFACTURER/SUPPLIER

Abbot Laboratories Ltd

PROBLEM

Laboratory repeat testing may be necessary on a significant proportion of samples due to high negative control rates resulting in invalid runs and to non-repeatable false positive results. Advice has been issued by the manufacturer (see Appendix 1).

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
- Directors and Managers of Pathology and Laboratory Services
- Device Managers
- Medical Directors
- Clinical Pathologists
- Nurse Directors
- Supplies Staff
- General Medical Practitioners
- Practice Nurses
- Clinical Pathologists
- Consultants in Communicable Disease
- Consultants in Genitourinary Medicine
- GUM Clinics
- Obstetricians
- Gynaecologists
- Antenatal Clinics
- Heads of Midwifery
- Family Planning Nurses
- Microbiologists
- Microbiology Departments
- Private Clinics

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.

IMMEDIATE ACTION

Laboratories should:

- Ensure repeat testing is being carried out according to the manufacturer's instructions (see Appendix 1).
- Consider the use of an alternative nucleic acid testing system
- Take every precaution to ensure the validity of results where change is not an option.

It is good laboratory practice to obtain a second sample where discrepant laboratory results are obtained.

ADVICE

NOTICE

BACKGROUND

1. Since February 2001, Abbot Laboratories Ltd has supplied a Device Correction to users of the LCx *Chlamydia trachomatis* Assay. This has informed users of reports of high negative control rates resulting in invalid runs and of non-repeatable false positive patient specimen results.
Laboratory users have been advised to repeat all patient samples that have S/CO ratios equal to or greater than 0.80 on initial testing. By doing this the company states that the product's performance remains within its claimed performance. This may be inconvenient and have resource implications for laboratories.
2. The Medical Devices Agency (MDA) has recently received a report from a laboratory user demonstrating that:
 - Repeat testing is being carried out on 9% of samples
 - A small number of results that were clearly positive on initial testing became clearly negative on retesting (differences of between 10- and 100- fold have occasionally been shown).
3. These data show that false amplification can give rise to high positive results.
4. The company has still not been able to eliminate the cause of the problem
5. Chlamydia testing requires the use of collection systems appropriate for the particular test kit used in the laboratory. A change in test kit by the laboratory may necessitate laboratories advising a change in the sample collection system used by the attendant health care providers. (See NIAIC Safety Notice SAN(NI)98/40 "Immunoassay Testing")

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Christine Brooker
Abbott Laboratories Ltd
Abbott House
Norden Road
Maidenhead
Berks
SL6 4XF

Tel: 01628 784041
Fax: 01628 644240

Enquires to the NIAIC should quote the reference number AN (NI) 2001/09 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
Email: brian.godfrey@dhsspsni.gov.uk

Tel: 02890 523714
Fax: 02890 523900

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) 2000/NIAIC. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided.

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



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