

SN (NI) 2002/15
DATE: 28 March 2002

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:
DR-70 GENERAL CANCER TEST

MANUFACTURER/SUPPLIER

AMD L – USA Manufacturer
SureScreen Diagnostics – UK Supplier (as part of their CD13+ cancer testing service)
DR-70 (UK) Ltd – UK Supplier

PROBLEM

There are insufficient data to substantiate claims being made about the clinical utility of the DR-70 in-vitro diagnostic blood test.

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
- Medical Directors
- Pathology Managers
- Pathology Laboratories eg
Biochemistry/Chemical Pathology
Haematology
Immunology
- Medical Oncologists
- Radiation Oncologists
- General Medical Practitioners
- Practice Nurses
- Private Clinics
- Trust Pharmacy Managers

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

The DR-70 cancer test result should not be used in isolation to make any screening, diagnostic or prognostic decisions.

BACKGROUND

- The Medical Devices Agency (MDA) has been made aware of concerns regarding the clinical utility of the DR-70 blood test and whether it is licensed by the MDA.
- The MDA does not approve, certify or license medical devices.
- According to the American manufacturer and UK suppliers, the DR-70 test is an immunoassay which quantifies the levels of fibrinogen degradation products (FDPs) in serum. The theoretical basis for use of this test is that individuals with cancer could be expected to have higher serum levels of FDPs than individuals without cancer.

SAFETY

NOTICE



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- The intended purpose of this test (as stated on the websites of the American manufacturer and UK suppliers) is “the detection of at least 13 different types of cancer”.
- The assay information booklet states that “The DR-70 test is useful as an aid in the detection of cancers.”
- The test is manufactured in the USA and is licensed by the US Food and Drug Administration (FDA) ‘for research use only’.
- **A report commissioned by the UK National Screening Committee concluded that ‘The available evidence is of insufficient quality and quantity to come to any firm conclusions regarding the likely usefulness of DR-70 as a screening test.’**
- The MDA continues to actively monitor the situation.

ENQUIRIES

Enquires to:

National Screening Committee:

Dr Muir-Gray
NSC Programme Director
Institute of Health Sciences
Old Road
Headington
Oxford
OX3 7LF

Tel: 01865 226 833

Enquires to the NIAIC should quote the reference number SN(NI) 2002/15 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) 2002/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

*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*