

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/55

Issued: 14 OCTOBER 2004

For:

<b>IMMEDIATE ACTION</b>	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<b>Medical Device/Equipment:</b> <b>BD Vacutainer® SST™, SST II™, and SST II Advance™</b> <b>blood collection tubes (glass and plastic).</b>	▶ ①
<b>Problem:</b> Incorrect test results (positive or negative bias) when using BD Vacutainer® SST™ blood collection tubes with specific named test systems (see Appendix 1).	▶ ②
<b>Action by:</b> <ul style="list-style-type: none"> <li>• Consultant Clinical Biochemists</li> <li>• Consultant Haematologists</li> <li>• Laboratory Managers</li> </ul>	▶ ③
<b>Action:</b> Laboratories should not use BD Vacutainer® SST™ blood collection tubes in combination with the test systems and markers identified in Appendix 1.  Affected laboratories should contact service users and request them not to take blood samples into these tubes for the determination of the listed markers.  Consultant Clinical Biochemists and Clinical Haematologists should: <ul style="list-style-type: none"> <li>• perform a risk analysis of results obtained with these device combinations</li> <li>• consider advising clinicians who have commissioned these tests on the need to recall or retest patients whose test results may have been affected.</li> </ul>	▶ ④
<b>Distributed by NIAIC to:</b> <p>Chief Executive of each HSS Board Chief Executive of each HSS Trust</p> <p>Chief Executive of each Agency NIAIC Liaison Officers</p> <p><b>For onward distribution see Section 5</b></p>	▶ ⑤
<b>Contacts</b> Details of manufacturer/supplier contacts, MHRA and NIAIC contacts.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> Report suspect test results from blood samples collected in BD Vacutainer® blood collection tubes to Becton Dickinson, the test system manufacturer and NIAIC.	▶ ⑦

**This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>**

## 1. DEVICE/EQUIPMENT:

BD Vacutainer® SST™, SST II™, and SST II Advance™ blood collection tubes (glass and plastic).

## 2. PROBLEM:

MHRA has received reports that incorrect results may be generated when using Vacutainer® SST™ blood collection tubes in combination with some test systems (see Appendix 1). The range of bias seen with assays on Beckman Coulter, Bayer and DPC test systems is listed in Appendix 2.

Becton Dickinson has identified that this problem is related to interference between a component of the tube (surfactant) and the listed test systems.

Becton Dickinson has issued technical bulletins to customers advising on alternative tubes that can be used.

Becton Dickinson will shortly make available tubes which have been reformulated with the aim of restoring performance for these assays. These reformulated tubes will be identified by lot numbers which will either end in the letter 'C' or begin with the number '5'.

## 3. ACTION BY:

- Consultant Clinical Biochemists
- Consultant Haematologists
- Laboratory Managers

## 4. ACTION:

Laboratories should not use BD Vacutainer® SST™ blood collection tubes in combination with the test systems and markers identified in Appendix 1.

Affected laboratories should contact service users and request them not to take blood samples into these tubes for the determination of the listed markers.

Consultant Clinical Biochemists and Clinical Haematologists should:

- perform a risk analysis of results obtained with these device combinations
- consider advising clinicians who have commissioned these tests on the need to recall or retest patients whose test results may have been affected.

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Clinical Governance Leads
- Clinical Directors
- Supplies Staff (RSS)
- Nursing Directors
- Medical Directors
- Directors of Pathology
- Pathology Managers
- Medical Oncologists
- Radiation Oncologists
- Consultant Biochemists
- Consultant Haematologists
- Consultant Physicians
- Endocrinologists
- Phlebotomists
- Biochemistry Laboratories
- Chemical Laboratories
- Haematology Laboratories
- Immunology Laboratories
- Microbiology Laboratories
- Independent Health and Social Care Providers – Private Clinics through HSS Board R&I Units

## 6. CONTACTS:

BD Preanalytical Systems  
Customer Services Team  
21 Between Towns Road  
Cowley  
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OX4 3LY

Tel: 01865 871 699

Fax: 01865 781 627

E-mail: [holly\\_streeter@europe.bd.com](mailto:holly_streeter@europe.bd.com)

Immunochemistry Support  
Bayer Plc  
Bayer House  
Strawberry Hill  
Newbury  
Berkshire RG14 1JA

Tel: 01635 566 222 (option 3)

Fax: 01635 566 274

E-mail: [immunochem.helpdesk@bayer.co.uk](mailto:immunochem.helpdesk@bayer.co.uk)

Adam Roberts  
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Oakley Court  
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Enquiries to the MHRA should quote reference number **2004/008/031/061/008** and be addressed to:

### Technical aspects:

Dr Khalid Razak or Ms Andrea Molyneaux  
Medicines & Healthcare products Regulatory  
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Hannibal House  
Elephant and Castle  
London SE1 6TQ

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### Clinical aspects:

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Enquires to NIAIC should quote reference number MDEA(NI)2004/55 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868

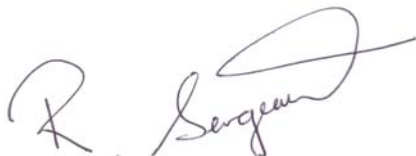
Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

Report suspect test results from blood samples collected in BD Vacutainer® blood collection tubes to Becton Dickinson, the test system manufacturer and NIAIC.

Robert Sergeant  
Operational Manager NIAIC

A handwritten signature in black ink, appearing to read 'R. Sergeant', is positioned below the printed name and title.

### 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 MDEA(NI)2004/01. 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](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*

## APPENDIX 1 to MDEA(NI)2004/55

Test bias seen when using BD Vacutainer® SST™ blood collection gel tubes with named test systems.

All variants of BD Vacutainer® SST™ gel blood collection tubes										
Test system	Total T3	Total T4	Cortisol	Insulin	Testo	CA15-3	Folate BA	Vit B12	FSH	ThCG
Beckman Coulter Access	●	○	○	○	○	○	○	○	○	○
Beckman Coulter Access 2	●	○	○	○	○	○	○	○	○	○
Beckman Coulter UniCel Dxl 800	●	○	○	○	○	○	○	○	○	○
Beckman Coulter SYNCRON LX I 725	●	○	○	○	○	○	○	○	○	○
Bayer ADVIA Centaur	●	●	●	●	●	●	●	●	■	■
Bayer ACS:180	●	●	●	●	●	●	●	●	■	■
DPC IMMULITE	●	●	●	○	○	○	○	○	○	○
DPC IMMULITE 1000	●	●	●	○	○	○	○	○	○	○
DPC IMMULITE 2000	●	●	●	○	○	○	○	○	○	○
DPC IMMULITE 2500	●	●	●	○	○	○	○	○	○	○

- Combination reported to give positive bias assay results
- Combination with no reported problem to MHRA
- Combination reported to give negative bias assay results

N.B. Free T3 and free T4 are not affected by this issue.

### Table Key:-

Total T3	Total triiodothyronine
Total T4	Total thyroxine
Testo	Testosterone
CA15-3	Breast cancer
Vit B12	Vitamin B12
FSH	Follicle stimulating hormone
ThCG	Total human chorionic gonadotropin

## APPENDIX 2 to MDEA(NI)2004/55

Range of bias seen with assays when using BD Vacutainer® SST™ blood collection gel tubes with named test systems.

Test systems	Range of bias*
Beckman Coulter Access Beckman Coulter Access 2 Beckman Coulter UniCel Dxl 800 Beckman Coulter SYNCRON LX I 725	Total T3: Positive bias between 20% and 58%
Bayer ADVIA Centaur Bayer ACS:180	Total T3: Positive bias between 0% and 58% Total T4: Positive bias between 9% and 33% Cortisol: Positive bias between 11% and 24% Insulin: Positive bias between 8% and 54% Testosterone: Positive bias between -4% and 28% CA15-3: Positive bias between 7% and 67% Folate: Positive bias between 14% and 72% Vitamin B12: Positive bias between 14% and 84%  ThCG: Negative bias between -10% and -43% FSH: Negative bias between -12% and -43%
DPC IMMULITE DPC IMMULITE 1000 DPC IMMULITE 2000 DPC IMMULITE 2500	Total T3: Positive bias between 20% and 58% Total T4: Positive bias between 3% and 34% Cortisol: Positive bias between 7% and 41%

\* Data from Beckton Dickinson or the test system manufacturer