ADVERSE INCIDENT REPORT FORM

Please tick ( ✓ ) the appropriate boxes

**Origin of report**
Hospital / Institution…………………………………………………………………………………………
Address………………………………………………………………………………………………………………
Laboratory………………………………………………………………………………………………………………
Reporter………………………………………………………………………………………………………………
Position………………………………………………………………………………………………………………
Telephone number……………………………………………………………………………………………………
Consultant-in-charge (if known)…………………………………………………………………………………
Local reference number (if available)……………………………………………………………………………

This report confirms a telephone report o a fax report o neither o

**Device description (tick one box only)**
- o Clinical Chemistry  o Microbiology  o Self/Home Testing
- o Haematology  o Cytopathology/Histopathology  o Genetic Testing
- o Immunology  o Extra-Lab Testing  o Specimen Receptacle

**Product**
- o Test kit - Colorimetric  o Instrumentation/  o Calibrators
- o Test kit - Immunoassay  o Software  o Reagent
- o Test kit - Other  o QC Materials  o Reagent strip

**Details of device - Instrumentation**
- Brand Name
- Analyte / Marker
- Manufacturer
- Telephone no:
- Supplier
- Telephone no:
- Batch No
- Expiry date
- Is there a CE mark?  Yes o No o

**Details of device - Kits, reagents and specimen receptacles**
- Brand Name
- Analyte / Marker
- Manufacturer
- Telephone no:
- Supplier
- Telephone no:
- Batch No
- Expiry date
- Is there a CE mark?  Yes o No o

**Nature of defect / details of incident**

**Contact name for further details**

**Action taken by staff / manufacturer / supplier**

Further details can be given on additional sheets if necessary

Please send completed form to: Medicines & Healthcare products Regulatory Agency
Adverse Incident Centre, 2nd Floor, Market Towers, 1Nine Elms Lane, London, SW8 5NQ,
by fax: 020 7084 3109 or e-mail: aic@mhra.gsi.gov.uk

FORMIVD (March 2003)