

Health Protection Agency Supplement Checklist

Possible Technical Adverse (TAI) Incident Report Form

HPA Checklist (PART I)	Date:
<i>Please e-mail parts I & II to: Standards Unit standards@HPA.org.uk & MHRA aic@medical-devices.gov.uk</i>	

For Standards Unit purposes only:	HPA/TAI/Year/
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<p>Was the correct sample type used?</p> <p>Were the appropriate storage conditions used?</p> <p>Was the equipment maintenance up to date?</p> <p>Were the appropriate SOPs followed?</p> <p>Were staff training records up to date)?</p> <p>What QC was performed?</p> <p>Were reference testing or confirmation performed?</p> <p>Was any retesting carried out?</p> <p>What were the consequences to patients?</p> <p>Suppliers / Manufacturer's view <i>Please state name of contact and outcome of discussion</i></p> <p>MHRA (Medicines and Healthcare Regulatory Agency) <i>Please state name of contact and outcome of discussion</i></p>	
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MHRA ADVERSE INCIDENT REPORT FORM (PART II)

Please tick (4) 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 <input type="checkbox"/> a fax report <input type="checkbox"/> neither <input type="checkbox"/>	

Device description (tick one box only)		
<input type="checkbox"/> Clinical Chemistry	<input type="checkbox"/> Microbiology	<input type="checkbox"/> Self/Home Testing
<input type="checkbox"/> Haematology	<input type="checkbox"/> Cytopathology/Histopathology	<input type="checkbox"/> Genetic Testing
<input type="checkbox"/> Immunology	<input type="checkbox"/> Extra-Lab Testing	<input type="checkbox"/> Specimen Receptacle

Product		
<input type="checkbox"/> Test kit – Colorimetric	<input type="checkbox"/> Instrumentation/ Software	<input type="checkbox"/> Calibrators
<input type="checkbox"/> Test kit – Immunoassay	<input type="checkbox"/> QC Materials	<input type="checkbox"/> Reagent
<input type="checkbox"/> Test kit – Other		<input type="checkbox"/> Reagent strip

Details of device – Instrumentation		
Product Name		
Model		
Manufacturer		
Supplier	Telephone no:	
Serial No		Approximate age
s there a CE mark? Yes <input type="checkbox"/> No <input type="checkbox"/>		

Please send completed form to: MHRA Adverse Incident Centre, Hannibal House, Elephant & Castle, London SE1 6TQ by fax (020 7972 8109) or e-mail (aic@medical-devices.gov.uk)

IN VITRO DIAGNOSTIC MEDICAL DEVICES

1.0 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 <input type="checkbox"/> No <input type="checkbox"/>		

Nature of defect / details of incident

Contact name for further details	
Telephone number	

Action taken by staff / manufacturer / supplier

Further details can be given on additional sheets if necessary