Annex 3

AFRICA MEDICAL DEVICES FORUM (AMDF) – TECHNICAL COMMITTEE UNDER THE AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH) INITIATIVE

REPORTING FORM FOR COMPLAINTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS

For **device end-users** – all adverse events/product problems should be reported to the manufacturer (and local authorized representative) as soon as you become aware. You can find manufacturer contact details in the instructions for use.

Adverse events may be: • Death of the patient, end-user or any other person happened or may have happened • Serious deterioration in health of the patient, end-user • or any other person happened or may have happened For IVDs: • A false negative result • A series of false positive results • Non-reproducible results • High or low readings, high or low-test results	**Product problems** may be: • Packaging – damaged, defective, suspect tampered • Labelling– insufficient instructions for use, illegible • Sampling – device doesn't collect/transfer specimen • Liquid – leak, splash • Mechanical – misalignment, jam • Electrical - unable to charge, power loss or fluctuation • Data – capture, display, or storage affecting product functionality • Software – network, program, algorithm, or security affecting product functionality • Environmental – noise, temperature, humidity/ moisture, fungal/bacterial growth, or dust affecting product functionality • Failure to calibrate • Increased rate of invalid or unreturnable test results • Obviously incorrect, inadequate or imprecise result or readings • Unable to obtain reading

For **device manufacturers** (and local authorized representative) – incidents that represent a serious public health threat should be **reported immediately and not later than 2 calendar days** to the relevant national regulatory authorities and to WHO (*e-mail: rapidalert@who.int*).
Other serious incidents including death or serious deterioration in health occurred or may have occurred for the patient, end-user or other individual should be **reported within 5 days** to the relevant national regulatory authorities and to WHO (*e-mail: rapidalert@who.int*).

1. Contact details of the reporting organization/person

Name of organization:	Street Name and No.:
City and postcode:	Country:
Name and position of contact person (for organization):	Email and telephone of contact person (for organization):
Report date:	Reporter's reference number:

2. Product details

Product name/commercial name/brand name:	Product code/catalogue number(s):
Serial number(s):	Model number(s):
Lot number/batch number(s):	Expiry date(s):
Associated devices/accessories (lot numbers/expiry dates):	Instructions for use version number:
Authorized representative name and contact details:	Manufacturer name and contact details:

Please attach a copy of the instructions for use and photographs of the device and its labelling.

3. Event/problem details

Event/problem description narrative (explain what went wrong with the product, and a description of the health effects [if applicable], i.e. clinical signs, symptoms, conditions as well as the overall health impact [death, life-threatening, indirect harm]), and the health/medical condition for which the device was being used.	
Date of the event/problem:	Number of devices involved:
Event classification: ❑ Serious ❑ Moderate ❑ Mild ❑ Other (specify):	% of device involved: Number of patients involved:
Operator/user at the time of the event/problem (please choose): ❑ Healthcare professional ❑ Patient/lay user ❑ Other (specify):	Has more than one user experienced the problem with the product? ❑ Yes ❑ No
Have you informed the distributor? ❑ Yes ❑ No	Date: What measures have been recommended?
Have you informed the manufacturer? ❑ Yes ❑ No	Date: What measures have been recommended?
Measures taken by the operator/user:	
Comments:	

Date of report:	Signature:

Disclaimer: The act of reporting an event is not an admission of manufacturer, user or patient liability for the event or its consequences. Submission of an adverse event report does not, in itself, represent a conclusion by the manufacturer that the content of this report is complete or confirmed, that the device(s) listed failed in any manner. It is also not a conclusion that the device caused or contributed to the adverse event.