**+0PUBLIC HEALTH IN-VITRO DIAGNOSTICS CONTROL LABORATORY**

**(MLSCN), 8, HARVEY ROAD, YABA, LAGOS.**

**POST-MARKET SURVEILLANCE OF IN VITRO DIAGNOSTICS**

**IVD COMPLAINT REPORTING FORM**

**MLSCN/IVDs/PMS/185**

**USER COMPLAINT FORM FOR REPORTING COMPLAINTS AND/OR ADVERSE EVENTS**

**RELATED TO IN VITRO DIAGNOSTICS**

Send to: Manufacturer

If serious or moderate adverse event, report to the relevant National Regulatory Authority (Email: [ivds@mlscn.gov.ng](mailto:ivds@mlscn.gov.ng). Phone: 09021765416, 08055660163) and WHO Prequalification of In Vitro Diagnostics Programme. *Email: diagnostics@who.int*

|  |  |
| --- | --- |
| Report Number: | Date received : |

**1. Contact details of the reporting person/organization**

|  |  |
| --- | --- |
| Name of person/organization: | Street Name and No.: |
| City and postcode: | Country: |
| Telephone: | Fax: |
| Name and position of contact person: | Email of contact person: |
| Report date: | Site report number: |

**2. Product details**

|  |  |
| --- | --- |
| Product name/commercial name/brand name: | Product code (catalogue number)(s): |
| Lot number/batch number/serial number: | Expiry date: |
| Associated devices/accessories / (lot numbers/expiry dates): | Instructions for use version number: |
| Distributor name and address: | Manufacturer name and address: |

**3. Event/problem details**

|  |  |
| --- | --- |
| Event/problem description narrative (explain what went wrong with the product and the observed or likely/probable consequences): | |
| Date of the event/problem: | Number of tests involved: |
| Event classification:   * Serious * Moderate * Mild * Other (specify): | % of tests involved : |
| Number of patients involved: |
| Operator/user at the time of the event/problem (please choose):   * MLS/Laboratory technician/technologist * (Non-laboratory) health worker * Other (specify): | Has more than one user experienced the problem with the product?   * Yes * No |
| Type of specimen used (please specify): | State reading time used: |
| 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: |

*Annex 3 – 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.*