In Vitro Diagnostic Products (IVDs): Deficiencies and/or Adverse Events Reporting Form

To be sent to Global Fund Quality Assurance Team at following Email address: healthproductqualityassurance@theglobalfund.org

This reporting form includes information regarding suspect adverse reaction, quality defect, deficiencies, or adverse events with health products circulated through the Global Fund (the “Health Information”). The Health Information may be circulated within the Global Fund organization and/or transferred to other international organizations, national regulatory authorities, health product manufacturers/suppliers, or procurement agencies.

#### Product Details

|  |  |
| --- | --- |
| Product name/commercial name/brand name:Click or tap here to enter text. | Catalogue number:Click or tap here to enter text. |
| Serial number/batch number/lot number:Click or tap here to enter text. | Expiry date:Click or tap here to enter text. |
| Associated devices/accessories:Click or tap here to enter text. | Instructions For Use (IFU) version number:Click or tap here to enter text. |
| Distributor name and address:Click or tap here to enter text. | Manufacturer name and address:Click or tap here to enter text. |

#### Event/Deficiencies Details

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| Event/deficiencies description narrative (explain what went wrong with the product and the observed or likely/probable consequences[[1]](#footnote-1)): Click or tap here to enter text. |
| Date and place of the event/problem:Click or tap here to enter text. | Number of tests involved:Click or tap here to enter text. |
| Are tests from different kits involved? [ ]  Yes [ ]  No | % of tests involved[[2]](#footnote-2):Click or tap here to enter text. |
| Operator at the time of the event/problem (please choose):[ ]  Laboratory technician/technologist[ ]  Non-laboratory trained health worker | Has more than one operator experienced the problem with the product?[ ]  Yes [ ]  No |
| Type of specimen used (please specify): | Reading time observed:Click or tap here to enter text. |
| Did you report the Event/deficiency to the regulatory authority in charge?[ ]  Yes [ ]  No | Date:Click or tap here to enter text. |
| What measures have been recommended?Click or tap here to enter text. |
| Name and address of any regulatory authority notified of the problem (if applicable)Click or tap here to enter text. |
| Have you informed the distributor/supplier?[ ]  Yes [ ] No | Date:Click or tap here to enter text. |
| What measures have been recommended?Click or tap here to enter text. |
| Have you informed the manufacturer?[ ]  Yes [ ] No | Date:Click or tap here to enter text. |
| What measures have been recommended?Click or tap here to enter text. |
| Measures taken by the user: Click or tap here to enter text. |
| Date of report: Click or tap here to enter text. |

1Note: Documents providing additional information can be attached to this form; please list them hereunder: Click or tap here to enter text.

#### Personal Information Section

**YOU MUST READ THE PRIVACY STATEMENT BEFORE COMPLETING THIS SECTION**

***PRIVACY STATEMENT***

***Available at following:*** [***https://www.theglobalfund.org/media/15326/corporate\_qa-reporting-forms\_privacy\_en.pdf***](https://www.theglobalfund.org/media/15326/corporate_qa-reporting-forms_privacy_en.pdf)

[ ]  I herewith acknowledge that I have read and understood the Privacy Statement applying to the personal information section

DateClick or tap here to enter text.

TitleClick or tap here to enter text.

SignatureClick or tap here to enter text.

#### Contact Details of the Reporting Organization

|  |  |
| --- | --- |
| Name of organization:Click or tap here to enter text. | Street Name and No.:Click or tap here to enter text. |
| City and postcode:Click or tap here to enter text. | Country:Click or tap here to enter text. |
| Telephone:Click or tap here to enter text. |
| Name of contact person:Click or tap here to enter text. | Email of contact person:Click or tap here to enter text. |

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| --- |
| This part is reserved for Global Fund Staff |
| Date of reception of report:Click or tap here to enter text. |
| Report Number:Click or tap here to enter text. |

1. Documents providing additional information can be attached to this form. [↑](#footnote-ref-1)
2. Please clarify how many tests out of the total number of tests used have the deficiency. [↑](#footnote-ref-2)