

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY



**IMPORTER/SUPPLIER FORM FOR REPORTING PROBLEMS AND/OR ADVERSE
EVENTS RELATED TO DIAGNOSTIC PRODUCTS**

Note: identities of reporter, patient and institution will remain confidential.

TMDA Internal Use Only	
Report Number:	Date received:
1. Contact details of the reporting company	
Name of company:	Importer/supplier/distributor (Please specify)
Postal address:	Street Name:
City:	District/Region:
Tel:	Mob: Fax:
Name and position of contact person:	
Email of contact person:	
2. Product details	
Product /commercial /brand name:	
Catalogue/Model number:	Serial /batch /lot number:
Manufacturing date:	Expiry date:
Name of associated devices/accessories:	Instructions for use version number:
Name of shop where the product was purchased:	
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 :	place of the event/problem:
Number of cases involved:	Are cases from different units involved? <input type="checkbox"/> Yes <input type="checkbox"/> No

<i>Operator at the time of the event/problem (please choose):</i>	<input type="checkbox"/> <i>Laboratory personnel</i>	<input type="checkbox"/> <i>Non-laboratory personnel</i>	<input type="checkbox"/> <i>other</i>
<i>Has more than one customer experienced the problem with the product?</i> <input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>			
<i>Type of specimen used (please specify):</i>	<i>Reading time observed:</i>		
	<i>Date:</i>		
<i>Have you informed the vendor?</i> <input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>			
<i>What measures have been recommended?</i>			
<i>Have you informed the manufacturer?</i>	<input type="checkbox"/> <i>Yes</i>	<input type="checkbox"/> <i>No</i>	<i>Date:</i>
<i>What measures have been recommended?</i>			
<i>Measures taken by the Importer/supplier:</i>			
<i>Date of report:</i>		<i>Signature:</i>	

Send to:

The Director General,
Tanzania Medicines and Medical Devices Authority (TMDA),
P. O. Box 1253, Makole Street, PSSSF Building, 7th Floor, Dodoma,
P.O. Box 77150, Off Mandela Road, Mabibo-External, Dar es Salaam
Tel: +255-22- 2450512/2450751/2452108, +255 68 445222/777 700002/685 701735
Email: info@tmda.go.tz