

Indian Pharmacopoeia Commission
Materiovigilance Programme of India (MvPI)
Ministry of Health and Family Welfare
Government of India

Draft In-vitro Diagnostic medical device (IVD-MD) adverse event reporting form for Comments

Published on: 17/02/2025

Last Date for Submission of Comments: 05/03/2025

Subject: Inviting comments from the stakeholders for the draft IVD-MD adverse event reporting form.

Based on the suggestions provided by the stakeholders, MvPI in collaboration with the CDSCO and the IVD manufacturers associations, has created this draft IVD reporting form. This form will help the stakeholders to capture the adverse events related to In-vitro Diagnostic medical device (IVD-MD). The content of this draft reporting form is not final and the text may be subjected to revision before being finalized by the MvPI.

Manufacturers, regulatory authorities, healthcare professionals, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments received after the last date will not be considered by the MvPI.

Please send any comments you may have on this draft document to naveen.v96@gov.in before the last date for comments.

Stakeholder Feedback form

S. No.	Page No.	Section Heading	Sub-heading	Current Text	Proposed Text	Explanation

Name: _____

Designation and Affiliation: _____



IN-VITRO DIAGNOSTIC MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI)

This form is intended to collect information on *In-Vitro Diagnostic* Medical Devices Adverse Event in India. The form is designed to be used by Domestic Manufacturer / Importer / Distributor of *In-Vitro Diagnostic* Medical Devices, Pathology Laboratory, Blood Donation Centre, Government Program In-charge and Healthcare Professionals with direct/indirect knowledge of In Vitro Diagnostic Medical Devices Adverse Event.

Disclaimer

Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event. Submission of a Medical Devices Adverse Event (MDAE) Report does not have any legal implication on the reporter.

Confidentiality

The patient/reporter's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the patient/reporter's identity in response to a request from the public.

Primary Information

1. Date of Report :
2. Type of Report : Initial Follow up Final Trend
3. Report Reference No. for MDMC¹ only : Centre Location Month – Year Case No.
4. Report Reference No. for MAH² only :

¹MDMC-Medical Device Adverse Event Monitoring Centre, ²MAH-Market Authorisation Holders

Reporter Details

1. Type of Reporter :

Manufacturer	<input type="checkbox"/>	Importer	<input type="checkbox"/>
Distributor	<input type="checkbox"/>	Healthcare Professional	<input type="checkbox"/>
Pathology Laboratory	<input type="checkbox"/>		
Blood Center	<input type="checkbox"/>		
Government Program In charge	<input type="checkbox"/>		
Others	<input type="checkbox"/>	Specify _____	
2. In case, Where the Reporter is not the Domestic Manufacturer / Importer of the product, Fill the Following Details: -
 - a) Has the Reporter Informed the Incident to the Domestic Manufacturer / Importer of the product? Yes No
 - b) If Yes, Event reported to Manufacturer / Importer via
 - i) Email
 - ii) Written communication
 - iii) Telephonic communication
 - iv) Other Specify _____
 - c) Is the Reporter also submitting the report on behalf of the manufacturer? Yes No
3. Reporter Contact Information :
 - a) Name :
 - b) Address :
 - c) Tel./ Mobile :
 - d) Email :

A) In-vitro Diagnostic Medical Device Details

Category		Sub-category	
1. Kits	<input type="checkbox"/>	1. Hematology	<input type="checkbox"/>
2. Reagents	<input type="checkbox"/>	2. Biochemistry	<input type="checkbox"/>
3. Calibrators	<input type="checkbox"/>	3. Microbiology	<input type="checkbox"/>
4. Controls	<input type="checkbox"/>	4. Immunology	<input type="checkbox"/>
5. Analyzers	<input type="checkbox"/>	5. Histopathology	<input type="checkbox"/>
6. Self-testing Kit	<input type="checkbox"/>	6. Molecular Biologics	<input type="checkbox"/>
7. IVD software	<input type="checkbox"/>	7. Gastroenterology & Urology	<input type="checkbox"/>
8. Others	<input type="checkbox"/> Specify _____	8. Gynecological	<input type="checkbox"/>
		9. Toxicology	<input type="checkbox"/>
		10. Others	<input type="checkbox"/> Specify _____

Generic In-Vitro Diagnostic Medical Device Name:

Trade Name/ Brand Name:

Details	Name	Address
Manufacturer		
Importer		
Distributor		
Marketed by		

1. IVD-MD Risk Classification as per Indian MDR 2017 : A B C D
2. License No. (Manufacturer/ Importer) :
3. Model No. :
4. Catalogue No. :
5. Lot/ Batch No. :
6. Serial No. :
7. Software Version (If applicable) :
8. Associated IVDs / Accessories :
9. UDI No. (If applicable) :
10. Manufacturing Date (If applicable) :
11. Expiration Date (If applicable) :
12. Last Calibration Date (DD/MM/YYYY) (If applicable) :
13. How long the IVD/ Instrument/ Analyser was in use :
14. Availability of IVD/ Instrument/ Analyser for evaluation : Yes No
 If no, was the IVD/ Instrument/ Analyser : Destroyed Still in use
 Returned to the Manufacturer/ Importer/ Distributor
 Other Specify _____
15. Is the IVD/ Instrument/ Analyser used as per Manufacturer claim/
 Instruction for use/ User manual : Yes No
 If no, Specify usage _____

B) Event Description

1. **Date of Event (DD/MM/YYYY) :**
2. **Type of Adverse Event:**
- Malfunction
 - Use error
 - Insufficient or Inadequate labelling or Instructions for use
 - Insufficient Reagent
 - False Positive
 - False Negative
 - Invalid Test
 - Wrong Result
 - Other
Specify _____
3. **Location of Event:**
- Hospital Blood Centre
 - Pathology Lab Home
 - Other specify _____
4. **IVD/Instrument/Analyser Operator:**
- Healthcare Professional Problem noticed prior to use
 - Laboratory operator Patient
 - Others specify _____
5. **IVD/Instrument/Analyser in use after incidence:** Yes No

6. **Serious Event:** Yes If yes, tick the appropriate reason
- a) Death (DD/MM/YYYY)
 - b) Life Threatening
 - c) Disability or Permanent Damage
 - d) Hospitalization/ Prolongation of Existing Hospitalization
 - e) Congenital Anomaly
 - f) Required Medical Intervention/ Permanent Impairment or Damage
 - g) Other (Important Medical Event)
Specify _____
7. **Non-serious Event**
8. **Whether other *in-vitro diagnostic* medical devices were used at same time with the above device:** Yes No
If yes, specify the name(s)/ use(s)
9. **Event outcome and reoccurrence information**
- a) Event abated after use is stopped/ reduced?
Yes No NA
 - b) Event reappeared after reintroduction?
Yes No NA

10. **Detail Description of Event:**

Note: Do you have any relevant diagnostics test/laboratory data/pictures/videos related to the events Yes No

If yes then kindly provide them while submitting the filled application form.

For Manufacturer/Authorized Representative Use Only

11. Frequency of Occurrence of Similar Adverse Event in India in Past 3 Years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)
12. Frequency of Occurrence of Similar Adverse Event Globally in Past 3 Years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)

C) Patient Information, History and Outcome	
1. Patient Hospital ID :	7. Patient outcomes a) Death (DD/MM/YYYY) <input type="checkbox"/> _____ b) Recovered (DD/MM/YYYY) <input type="checkbox"/> _____ c) Not yet recovered <input type="checkbox"/> d) Stable <input type="checkbox"/> e) Other <input type="checkbox"/> Specify _____
2. Patient Initial :	
3. Age :	
4. Gender : Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender <input type="checkbox"/>	
5. Weight :	
6. Other relevant history : (including pre-existing conditions, treatment, allergy)	

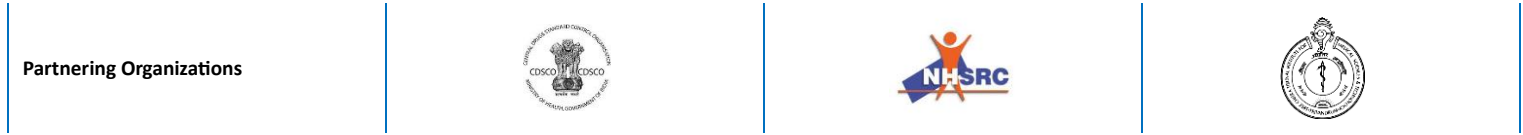
D) Healthcare Facility Information (If available)	
1. Name :	
2. Address :	
3. Contact Person Name at the Site of Event :	
4. Tel. No. /Mobile No. :	
5. Email :	

E) IVD Medical Device Adverse Event Assessment / False Positive / False Negative / Invalid Test / Wrong Result	
1. Immediate Action Taken:	
2. Suspected Root Cause of Problem:	
3. In Your Opinion, Which of the Following Best Describe the Association between Suspected In vitro diagnostic Medical Device(s) and Adverse Event? a) Not related <input type="checkbox"/> b) Possible <input type="checkbox"/> c) Probable <input type="checkbox"/> d) Related <input type="checkbox"/>	

F) For Manufacturer/Authorized Representative / Pathology Laboratory, Blood Donation Center, Government Program In charge, Healthcare Professionals and License Holder Only	
1. Investigation Needed? Yes <input type="checkbox"/> No <input type="checkbox"/>	
2. Investigation Action Taken with Timeline:	
3. Root Cause of Problem (Applicable for follow up/ final reports):	
4. Corrective and Preventive action (CAPA) taken:	

Where to report?

Duly filled Medical Device Adverse Event Reporting Form can be send to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, or email to mvpi-ipc@gov.in , shatrunjay.ipc@gov.in or Call on Helpline no. 1800 180 3024 to report Adverse event.



List of Document to be attached

	Healthcare professionals	Domestic Manufacturer	Importer	Government Program	Blood Centre	Pathology Laboratory
Product/ premises license copy	-	√	√	√	√	-
Copy of Invoice	-	-	√	√	√	√
Copy of purchase bill	-	-	-	√	√	√
IFU/ Operator Manual/ Product Brochure/ Product labels	√	√	√	√	√	√
Video/ Photograph of used/ tested kit	√	√	√	√	√	√

Draft