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 MDMC[1] only : Centre Location Month – Year Case No.
4. Report Reference No. for MAH[2] only :

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

Reporter Details

1. Type of Reporter :
   - Manufacturer ☐
   - Importer ☐
   - Distributor ☐
   - Healthcare Professional ☐
   - Pathology Laboratory ☐
   - Blood Center ☐
   - Government Program In charge ☐
   - Others ☐ 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, Date of which Manufacturer/ Importer was made aware (DD/MM/YYYY)
     - 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) Organisation :
   - c) Address :
   - d) Tel./ Mobile :
   - e) Email :

A) *In-vitro Diagnostic* Medical Device Details

Category	Sub-category
1. Kits ☐	1. Hematology ☐
2. Reagents ☐	2. Biochemistry ☐
3. Calibrators ☐	3. Microbiology ☐
4. Controls ☐	4. Immunology ☐
5. Analyzers ☐	5. Histopathology ☐
6. Specimen Receptacles ☐	6. Molecular Biology ☐
7. Self-testing Kit ☐	7. Gastroenterology & Urology ☐
8. IVD software ☐	8. Gynecological ☐
9. Others ☐ Specify	9. Toxicology ☐
	10. Others ☐ 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. (If applicable) :
4. Catalogue No. :
5. Lot/ Batch No. :
6. Serial No. (If applicable) :
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 Medical Device was in use :
14. Availability of IVD Medical Device for evaluation : Yes ☐ No ☐
    If no, Status of IVD Medical Device and location (specify) : Destroyed ☐ Still in use ☐
    Returned to the Manufacturer/ Importer/ Distributor ☐
    Other ☐ Specify
15. Is the IVD Medical Device 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 Medical Device Operator:**

Healthcare Professional ☐ Problem noticed prior to use ☐

Laboratory operator ☐ Patient ☐

Others ☐ specify

5. **IVD Medical Device 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 ☐

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 during retesting/ reuse?

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 :
2. Patient Initial :
3. Age :
4. Gender : Male ☐ Female ☐ Transgender ☐
5. Weight :
6. Other relevant history :
   (including pre-existing conditions, treatment, allergy)

7. Patient outcomes
   a) Death (DD/MM/YYYY) ☐
   b) Recovered (DD/MM/YYYY) ☐
   c) Not yet recovered ☐
   d) Stable ☐
   e) Other ☐
   Specify

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: Date of 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 ☐ b) Possible ☐ c) Probable ☐ d) Related ☐

F) For Manufacturer/Authorized Representative / Pathology Laboratory, Blood Donation Center, Government Program In charge, Healthcare Professionals and License Holder Only

1. Investigation Needed? Yes ☐ No ☐
2. Investigation Action Taken with Timeline:
3. Root Cause of Problem (Applicable for follow up/ final reports):

4. Corrective and Preventive action (CAPA) taken: Date of CAPA implemented on: ☐

5. Field Safety Notice/ Field Safety Corrective Action Initiated: Yes ☐ No ☐
   If Yes, date of Field Safety Notice issued/ Expected date of completion of Field Safety Corrective Action (DD/MM/YYYY):

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.

Partnering Organizations

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	✓	✓	✓	✓	✓	✓

Feedback: kind provide your feedback in respect to the usage of this form and regarding Materiovigilance Programme of India

(Your valuable feedback will help us progress effectively)