REPORT OF SUSPECTED ADVERSE DRUG REACTION (ADR)

Please complete and forward this form to Biotest AG Corporate Drug Safety, Landsteinerstr. 5, 63303 Dreieich - phone:+49 6103 801 756; fax: +49 6103 801 854 or drugsafety@biotest.com

☐ **Initial report** ☐ **Follow-up #**_____ **Case ID**_____ **Date of this report** ____ /_____ /_____
dd mon yyyy

Product

Biotest product _____ **Rate of infusion** _____**ml/60 min**

Indication _____ **Please specify if other unit** _____

Batch No _____ **Total volume infused** _____**ml**

Temperature of infusion _____**°C**

Date of last administration prior to the reported adverse event ____ /_____ /_____
dd mon yyyy

Start time _____:_____ **Duration of drug administration** _____ (add unit)
hh min

Patient Data

Patient initials _____ **Gender** ☐ Male ☐ Female **Age** _____ **Weight** _____ kg **Height** _____ cm

Pregnancy ☐ Yes ☐ No ☐ Unknown **If yes, estimated date of delivery** ____ /_____ /_____
dd mon yyyy

Adverse drug reactions (ADRs)

ADR/Diagnosis **Diagnosis and/or symptoms of the ADR (please list most significant adverse reactions first):**	**Onset date and time**	**Duration** (add unit)
_____	____ /_____ /_____/_____:_____/_____ dd mon yyyy hh mm	
_____	____ /_____ /_____/_____:_____/_____ dd mon yyyy hh mm	
_____	____ /_____ /_____/_____:_____/_____ dd mon yyyy hh mm	

Additional information/Description of suspected adverse drug reaction (s)

_____

_____

_____

Previous Reactions

Did a similar event occur in this patient before? ☐ Yes ☐ No

Related to similar drugs? ☐ Yes ☐ No **If yes, please specify** _____

Outcome

☐ **Recovered/resolved on** ____ /_____ /_____ ☐ **Recovering/resolving** ☐ **Not recovered/not resolved**
dd mon yyyy

☐ **Resolved with sequelea** ☐ **Fatal** ☐ **Unknown**

Immediate Action Taken

☐ **None** ☐ **Drug withdrawn** ☐ **Reduced dose/reduced infusion rate** Please specify_____

☐ **Other measures to treat the suspected adverse drug reaction(s)** Please specify_____

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Biotest

Seriousness Criteria

☐ **Not serious**

☐ **Serious, please select at least one of the following criteria for seriousness:**

☐ **Fatal** Date of death ____ /____ /____ (dd / mon / yyyy) **Autopsy** ☐ No ☐ Planned ☐ Status unknown

☐ **Life-threatening**

☐ **Hospitalization** Date of admission ____ /____ /____ (dd / mon / yyyy) Date of discharge ____ /____ /____ (dd / mon / yyyy) ☐ **Ongoing**

☐ **Prolonged hospitalization**

☐ **Persistent or significant disability / Incapacity**

☐ **Results in a congenital anomaly / Birth defect**

☐ **Other medically important condition, please specify** (i.e. events that do not meet the standard criteria for seriousness, but based on medical judgment are considered serious as they may jeopardise the patient and may require medical or surgical intervention to prevent the event meeting the standard criteria for seriousness)

_____

Relevant Medical History

Allergies ☐ Yes ☐ No Please specify _____

IgA deficiency ☐ Yes ☐ No Please specify _____

Other relevant medical history	Treated with

Other concomitant medications _____

_____

Reporter Information

Has this case been reported to the national authority or any other organization? ☐ Yes ☐ No

If yes, to whom _____ **Date** ____ /____ /____ (dd / mon / yyyy)

☐ I disagree with transmission of my name and address to authorities

(**NOTE**: depending on national law, this option is **not valid** for Health Care Professionals!)

Reporter (name institution, address, phone, fax, e-mail)

☐ Physician ☐ Pharmacist ☐ Nurse ☐ Patient ☐ Other

Date ____ /____ /____ (dd / mon / yyyy) **Signature** _____

(stamp, if applicable)