Report on Adverse Drug Reactions to

Biotest AG, Dep. Corporate Drug Safety, Landsteinerstr. 5, 63303 Dreieich, Germany
Tel: +49 (0) 6103 801-756, Fax: +49 (0) 6103 801-854, e-mail: drugsafety@biotest.de

Biotest From Nature for Life

Code-No.	Pat. Init. Last Name	Pat. Init. First Name	Birthdate Day	Birthdate Months	Birthdate Year	Gender ☐ M ☐ F	Height (cm)	Weight (kg)	Occupation	Ethnicity	Months of Pregnancy:

Adverse drug reaction observed on: Duration:

Product/Preparation	**Daily Dosage**	**Application**	from **administered**	to	**Reason**
1. Batch-No.:					
2. Batch-No.:					
3. Batch-No.:					
4. Batch-No.:					

Suspected causal relation to: Product No.. 1 2 3 4	Suspected product previously administered ☐ yes ☐ no	tolerated ☐ yes ☐ no	reexposition if applicable ☐ yes ☐ no

Underlying disease: **Concomitant diseases:**

Anamn. characteristics: ☐ nicotine ☐ alcohol ☐ contraceptives ☐ pacemaker ☐ implants ☐ radiotherapy ☐ physical therapy ☐ diet ☐ allergies ☐ metabolic defect° ☐ medicinal drug abuse other:_____

°additinal explanation:

Changes of laboratory results related to the adverse drug reaction: *)

Progression and therapy of the adverse drug reaction: life threatening ☐ yes ☐ no Hospitalisation? *) ☐ yes ☐ no

Outcome of the adverse drug reaction:

☐ recovered ☐ recovered with sequelae ☐ not yet recovered ☐ unknown

☐ Death: [☐ drug contribution possible ☐ result of the ADR ☐ without drug contribution]

Cause of death:

Authopsy:*) ☐ yes ☐ no

Assessment of causality: ☐ certain ☐ probable ☐ possible ☐ unlikely ☐ unassessed ☐ unassesable

Other comments:

Who is informed, please specify: (i.e. local authority, other manufacturer, medical/pharmaceutical organisation)

Name of physician/pharmacist: Discipline: Address: Clinic ☐ yes ☐ no (Stamp if applicable)	Name of reporting patient: Address:	Date: Signature

*) attach medical report if applicable