DIVISION OF AIDS TABLE FOR GRADING THE SEVERITY OF ADULT AND PEDIATRIC ADVERSE EVENTS PUBLISH DATE: DECEMBER, 2004

LABORATORY				
PARAMETER	GRADE 1 MILD	GRADE 2 MODERATE	GRADE 3 SEVERE	GRADE 4 POTENTIALLY LIFE-THREATENING
URINALYSIS	*Standard International Units are listed in Italics*			
Hematuria (microscopic)	6 – 10 RBC/HPF	> 10 RBC/HPF	Gross, with or without clots OR with RBC casts	Transfusion indicated
Proteinuria, random collection	1 +	2 – 3 +	4 +	NA
Proteinuria, 24 hour collection				
Adult and Pediatric ≥ 10 years	200 – 999 mg/24 h *0.200 – 0.999 g/d*	1,000 – 1,999 mg/24 h *1.000 – 1.999 g/d*	2,000 – 3,500 mg/24 h *2.000 – 3.500 g/d*	> 3,500 mg/24 h *> 3.500 g/d*
Pediatric > 3 mo - < 10 years	201 – 499 mg/m^2/24 h *0.201 – 0.499 g/d*	500 – 799 mg/m^2/24 h *0.500 – 0.799 g/d*	800 – 1,000 mg/m^2/24 h *0.800 – 1.000 g/d*	> 1,000 mg/ m^2/24 h *> 1.000 g/d*

*Values are for term infants.

† Use age and sex appropriate values (e.g., bilirubin), including preterm infants.

Appendix 2)

(Format)

Report on unknown serious adverse events

Day/Month/Year

To the Minister of Health, Labor and Welfare

We report the following unknown serious adverse event related to the study.

1. Information on the reporter
   (1) Name of the study site and job title/name of the head of the study site:
   (2) Name of the principal investigator:
   (3) Title of the study:
   (4) Study number ID:
   (*The unique number for specifying the study, such as identification number assigned in advance by the public database of study protocol, should be entered. The same number should be used for reports on the relevant study in all study-related institutes.)
   (5) Contact number: TEL: FAX:
   e-mail:

2. Description of the report
   (1) The site where the relevant adverse event occurred:
   ☐ Our site ☐ Other joint study site (Name of the site:)

   (2) Name and course of the serious adverse event
   (Onset date, reason why the relevant event is considered to be serious, details of intervention, causal relationship, course, outcome, etc. should be entered briefly.)

   (3) Measures taken for the serious adverse event
   (Discontinuation of new enrollment, revision of the informed consent form with explanatory statement, re-consent by the other subjects, etc.)

   (4) Review date at the study ethics committee, summary of the review, results, required measures, etc.

   (5) Notification to joint study sites:
   Joint study site
   ☐ Absent ☐ Present (total No. of sites (including the relevant site):)
   Relevant information is notified or not notified
   ☐ Not notified ☐ Notified