

P1106 Site Guidance on Laboratory Assessments: Recording Value on Forms and Determining Grade

Lab Assessment	Arm for Required Assessment	Grading Source	FORM	→ GRADING
Hemoglobin (HGB)	1, 2, 3, 4, 5, 6	If LBW ¹ : Appendix IV	LBW0143	→ Code on this form as 8
			TGW0004	→ Grade per Appendix IV, Anemia
		If NBW: DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
Serum Creatinine (CRET) ²	1, 2, 3, 4, 5, 6	DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
ALT/SGPT ²	1, 2, 3, 4, 5, 6	DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
GGT	1, 2, 3, 4	N/A	LBW0143	→ Code on this form as 8
Potassium (K)	5,6	DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
Calcium (CA)	5, 6	DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
Serum Osmolality	5, 6	N/A	LBW0143	→ N/A
<p><i>Additional diagnoses, clinical events, and/or laboratory abnormalities may be recorded if the site clinical care provider thinks they represent significant morbidities not already captured by the established list of diagnoses, per protocol Section 6.1. Assessments that have been previously entered in CRFs are indicated below as examples.</i></p>				
ANC	N/A	If LBW ¹ : Appendix IV	LBW0143	→ Code on this form as 8
			TGW0004	→ Grade per Appendix IV, Neutropenia
		If NBW: DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
Platelet Count	N/A	If LBW ¹ : Appendix IV	LBW0143	→ Code on this form as 8
			TGW0004	→ Grade per Appendix IV, Thrombocytopenia
		If NBW: DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
Sodium (NA)	N/A	DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
Alkaline Phosphatase (ALP) ²	N/A	DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
Inorganic Phosphate (P)	N/A	DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
Organic Phosphate (P)	N/A	DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
Total Bilirubin (TBIL) ²	N/A	DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
AST/SGOT ²	N/A	DAIDS Grading Table	LBW0143	→ Grade per DAIDS table
Other laboratory adverse events determined not to be related to LBW	N/A	DAIDS Grading Table	LBW0143	→ Grade per DAIDS table

LBW = low birth weight (<2500 grams); NBW = normal birth weight (≥2500 grams to ≤4000 grams)

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1. **Per protocol Section 7.1, modified in Letter of Amendment #3, dated 30 January 2018, to P1106 Protocol Version 1.0:** “A site investigator may determine that a LBW infant’s adverse event, even if included in the list of diagnoses/clinical events in Appendix IV, does not meet the relationship to LBW under the Expected Adverse Event category. If that is the case, these adverse events will be assessed as unexpected adverse events and graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 1.0, dated December 2004, (Clarification dated August 2009) (e.g., sepsis or a laboratory assessment may or may not fit into the low birth weight-related Expected Adverse Events). Investigators should use clinical judgment in determining which category is appropriate for LBW infants (Appendix IV, Table for Grading Expected Adverse Events, or DAIDS Table for Grading). The study team should be consulted if questions arise.”

2. **Normal Neonatal Values for LBW Infants (according to gestational age at birth (weeks), birth and age after birth)**

Serum Creatinine (µmol/L):

Gestational age at birth (Weeks)	Age	Lower Limit of Normal (LLN) to Upper Limit of Normal (ULN)
24-28	1 day	25 - 136
29-36	1 day	27 - 175
26-34	1 week	69 - 141
	2 week	45 - 99
	3-4 week	39 - 71
	5-6 week	42 - 62
	7-9 week	39 - 48

Alkaline phosphatase (ALP) (IU/L):

Gestational age at birth (Weeks)	Lower Limit of Normal (LLN) to Upper Limit of Normal (ULN)
26-27	35 - 604
28-29	119 - 465
30-31	112 - 450
32-33	110 - 398
34-35	113 - 320
36	88 - 326
>36	28 - 300

ALT/SGPT: 6 – 40 IU/l **AST/SGOT:** 20 – 100 IU/L

Source:

Rennie, Janet M., and N.R.C. Robertson. *Robertson’s Textbook of Neonatology*. Edinburgh: Elsevier/Churchill Livingstone, 2005. Print.