

Analytical Measurement Range (AMR) and Clinical Reportable Range (CRR)

Analyte	Mfg's AMR	Low Value Verified	High Value Verified	Reportable Range	Dilutions	CRR	DAIDS Toxicity Grade 4
ALT	5-700 U/L	2.5	770	5-700	1:10	5-7000	>381
WBC	0.5-25 10 ⁹ /uL	1.0	25	1.0-25	1:10	1.0-250	<1.0

Analytical Sensitivity and Specificity- See below for examples of how to enter information from the package insert into the summary form.

Chemistry

Summary of Manufacturer's Claims for Sensitivity and Specificity		
Analyte	Specificity (Interfering Substances)	Sensitivity
ALT	Icterus – No significant effect Hemolysis – No significant effect Lipemia – No significant effect; >Abs flagging may occur Other –Calcium dobesilate may cause low results	5 U/L
AST	Icterus – No significant effect Hemolysis – No significant effect Lipemia – No significant effect; >Abs flagging may occur	5 U/L
Albumin	Icterus –No significant effect Hemolysis- No significant effect Lipemia- No significant effect	0.2 g/dL

Hematology

Summary of Manufacturer's Claims for Sensitivity and Specificity		
Analyte	Specificity (Interfering Substances)	Sensitivity
WBC:	Unlysed Red Cells - False increase Multiple Myeloma - False increase Leukemia - False decrease Chemotherapy - False decrease Cryoglobulins - False increase WBC Agglutination - False decrease PLT Agglutination - False increase	0 K/uL
RBC:	Agglutinated RBC's - False decrease & falsely elevated MCH, MCHC & MCV Cold Agglutinins - False decrease & falsely elevated MCV	0 10 ¹² /L
HGB	High WBC - An extremely high WBC will cause excessive light scatter. In these cases use reference methods.	0 g/dL

