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	0 K/uL			
	Multiple Myeloma - False increase				
	Leukemia - False decrease				
	Chemotherapy - False decrease				
	Cryoglobulins - False increase				
	WBC Agglutination - False decrease				
	PLT Agglutination - False increase				
RBC:	Agglutinated RBC's - False decrease & falsely elevated MCH, MCHC & MCV	0 10 ¹² /L			
	Cold Agglutinins - False decrease & falsely elevated MCV				
HGB	High WBC - An extremely high WBC will cause excessive light scatter. In these cases use reference methods.	0 g/dL			

	Lipemia - Significant interference - Use a reference method and plasma	
	blank.	
	Turbidity - False increase, abnormal MCH, MCHC values & an	
	increased baseline on the leading edge of the WBC histogram.	
	Fetal Blood - False increase.	
HCT	RBC agglutination - Inaccurate results.	0 g/dL
MCV	RBC agglutination - Inaccurate results.	N/A
IVICV	Large Platelets (excessive numbers) - Inaccurate results	IN//
	High WBC's - Inaccurate results	
MCH	Calculated based on HGB & RBC -refer to those for MCH limitations.	N/A
MCHC	Calculated based on HBG & HCT - refer to those for MCHC limitations.	N/A
RDW	Calculated based on RBC - refer to RBC count for limitations	N/A
PLTs	Microcytes, Schistocytes & WBC Fragments - False increase	0 K/uL
1 210	RBC Agglutination - Falsely decrease	OTGE
	Giant Platelets (large number) - False decrease	
	Chemotherapy - False decrease	
	Hemolysis - False increase	
	ACD Blood - False decrease	
	Increased Triglycerides and/or Cholesterol - Inaccurate results	
	Platelet Agglutination - False decrease	
MPV	Giant Platelets - Inaccurate results	N/A
	Microcytes, Schistocytes & WBC Fragments - Inaccurate results	
	RBC Agglutination - Inaccurate results	
	Chemotherapy - Inaccurate results	
LYM % &	Erythroblasts - False increase	0 K/uL
Absolute	Parasites - False increase	
	Unlysed RBC's - False increase	
	WBC limitations - Pertains to differential enumeration also	
MON % &	Large lymphocytes - False increase	0 K/uL
Absolute	Atypical Lymphocytes - False increase	
	Blasts - False increase	
	Basophils (excessive numbers) - False increase	
	WBC limitations - Pertains to differential enumeration also	
NEU % &	Eosinophils (excessive numbers) - Inaccurate results	0 K/uL
Absolute	Immature granulocytes - Inaccurate results	
	Plasma cells - Inaccurate results	
	WBC limitations - Pertains to differential enumeration also	
EOS %	Abnormal granules - Inaccurate results	0 K/uL
Absolute	WBC limitations - Pertains to differential enumeration also	
BAS % &		0 K/uL
Absolute	WBC limitations - Pertains to differential enumeration also	