

Appendix C: Toxicity Table – DMID Adult toxicity Table, November, 2007**ABBREVIATIONS:** Abbreviations utilized in the Table:

ULN = Upper Limit of Normal	LLN = Lower Limit of Normal
R _x = Therapy	Req = Required
Mod = Moderate	IV = Intravenous
ADL = Activities of Daily Living	Dec = Decreased

ESTIMATING SEVERITY GRADE

For abnormalities NOT found elsewhere in the Toxicity Tables use the scale below to estimate grade of severity:

GRADE 1	Mild	Transient or mild discomfort (< 48 hours); no medical intervention/therapy required
GRADE 2	Moderate	Mild to moderate limitation in activity - some assistance may be needed; no or minimal medical intervention/therapy required
GRADE 3	Severe	Marked limitation in activity, some assistance usually required; medical intervention/therapy required, hospitalizations possible
GRADE 4	Life-threatening	Extreme limitation in activity, significant assistance required; significant medical intervention/therapy required, hospitalization or hospice care probable

The grading of the laboratory AEs will be based on the DMID toxicity table.

SERIOUS OR LIFE-THREATENING AEs

ANY clinical event deemed by the clinician to be serious or life-threatening should be considered a grade 4 event. Clinical events considered to be serious or life-threatening include, but are not limited to: seizures, coma, tetany, diabetic ketoacidosis, disseminated intravascular coagulation, diffuse petechiae, paralysis, acute psychosis, severe depression.

HEMATOLOGY				
	Grade 1	Grade 2	Grade 3	Grade 4
Hemoglobin (gm/dL)				
Male, 18-21 yrs				
Male, > 21 yrs	11.8-13.0	10.5-11.7	9.2-10.4	< 9.2
Female, 18-21 yrs	12.5-13.7	11.2-12.4	9.9-11.1	< 9.9
Female, >21 yrs	11.0-12.2	9.7-10.9	8.4-9.6	<8.3
	10.6-11.8	9.3-10.5	8.0-9.2	<8.0
Absolute Neutrophil Count (mm ³)	1000-1490	750-999	500-749	<500
Platelets (mm ³)	100,000-125,000	50,000-99,999	20,000-49,999	<20,000
WBCs (mm ³)				
Decrease	3,100-4,000	2,500-3,999	1,800-2,400	<7,999
Increase	11,100-13,000	15,000		

CHEMISTRIES				
	Grade 1	Grade 2	Grade 3	Grade 4
Sodium (mEq/L) Hyponatremia	130-134	123-129	116-122	< 116 or abnormal sodium <i>with</i> mental status changes or seizures
Sodium (mEq/L) Hypernatremia	150-154	155-163	164-171	> 171 or abnormal sodium <i>with</i> mental status changes or seizures
Potassium (mEq/L) Hypokalemia	3.0 - 3.4	2.5 - 2.9	2.0 - 2.4 or intensive replacement therapy or hospitalization required	< 2.0 or abnormal potassium <i>with</i> paresis, ileus or life-threatening arrhythmia
Potassium (mEq/L) Hyperkalemia	5.6 - 6.0	6.1 - 6.5	6.6 - 7.0	> 7.0 or abnormal potassium <i>with</i> life-threatening arrhythmia
Random Glucose (mg/dL) Hypoglycemia	50-59	40-49	30-39	<30 or abnormal glucose <i>with</i> mental status changes or coma

CHEMISTRIES (continued)

	Grade 1	Grade 2	Grade 3	Grade 4
Glucose mg/dL Hyperglycemia (nonfasting and no prior diabetes)	116 - 160	161- 250	251 - 500	> 500 or abnormal glucose <i>with</i> ketoacidosis or seizures
Calcium mg/dL Hypocalcemia (corrected for albumin)	8.2 - 7.8	7.7 - 7.0	6.9 - 6.1	< 6.1 or abnormal calcium <i>with</i> life threatening arrhythmia or tetany
Calcium mg/dL Hypercalcemia (correct for albumin)	10.6 - 11.5	11.6 - 12.5	12.6 - 13.5	> 13.5 or abnormal calcium <i>with</i> life threatening arrhythmia

CHEMISTRIES (continued)

	Grade 1	Grade 2	Grade 3	Grade 4
Bilirubin (mg/dl) Hyperbilirubinemia (when accompanied by any increase in other liver function test)	1.1 - <1.25 x ULN	1.25 - <1.5 x ULN	1.5 – 1.75 x ULN	> 1.75 x ULN
Bilirubin (mg/dl) Hyperbilirubinemia (when other liver function are in the normal range)	1.1 - <1.5 x ULN	1.5 - <2.0 x ULN	2.0 – 3.0 x ULN	> 3.0 x ULN
BUN	1.25 - 2.5 x ULN	2.6 - 5 x ULN	5.1 - 10 x ULN	> 10 x ULN
Creatinine	1.1 - 1.5 x ULN	1.6 - 3.0 x ULN	3.1 - 6 x ULN	> 6 x ULN or dialysis required

ENZYMES				
	Grade 1	Grade 2	Grade 3	Grade 4
AST (SGOT)	1.1 - <2.0 x ULN	2.0 – <3.0 x ULN	3.0 – 8.0 x ULN	> 8 x ULN
ALT (SGPT)	1.1 - <2.0 x ULN	2.0 – <3.0 x ULN	3.0 – 8.0 x ULN	> 8 x ULN
Alkaline Phosphatase	1.1 - <2.0 x ULN	2.0 – <3.0 x ULN	3.0 – 8.0 x ULN	> 8 x ULN

URINALYSIS				
	Grade 1	Grade 2	Grade 3	Grade 4
Proteinuria	1+ or 200 mg - 1 gm loss/day	2-3+ or 1- 2 gm loss/day	4+ or 2-3.5 gm loss/day	nephrotic syndrome or > 3.5 gm loss/day
Hematuria	microscopic only 6-10rbc/hpf	gross, no clots >10 rbc/hpf	gross, with or without clots, OR red blood cell casts	obstructive or required transfusion

CARDIOVASCULAR				
	Grade 1	Grade 2	Grade 3	Grade 4
Cardiac Rhythm		asymptomatic, transient signs, no Rx required	recurrent/persistent; symptomatic Rx required	unstable dysrhythmia; hospitalization and treatment required
Hypertension	transient increase > 20 mm/Hg; no treatment	recurrent, chronic increase > 20mm/Hg. /treatment required	acute treatment required; outpatient treatment or hospitalization possible	end organ damage or hospitalization required

CARDIOVASCULAR (continued)				
	Grade 1	Grade 2	Grade 3	Grade 4
Hypotension	transient orthostatic hypotension with heart rate increased by <20 beat/min or decreased by <10 mm Hg systolic BP, No treatment required	symptoms due to orthostatic hypotension or BP decreased by <20 mm Hg systolic; correctable with oral fluid treatment	requires IV fluids; no hospitalization required	mean arterial pressure <60mm/ Hg or end organ damage or shock; requires hospitalization and vasopressor treatment
Pericarditis	minimal effusion	mild/moderate asymptomatic effusion, no treatment	symptomatic effusion; pain; EKG changes	tamponade; pericardiocentesis or surgery required
Hemorrhage, Blood Loss	microscopic/occult	mild, no transfusion	gross blood loss; 1-2 units transfused	massive blood loss; > 3 units transfused

RESPIRATORY				
	Grade 1	Grade 2	Grade 3	Grade 4
Cough	transient- no treatment	persistent cough; treatment responsive	Paroxysmal cough; uncontrolled with treatment	-----
Bronchospasm, Acute	transient; no treatment; 70% - 80% FEV ₁ of peak flow	requires treatment; normalizes with bronchodilator; FEV ₁ 50% - 70% (of peak flow)	no normalization with bronchodilator; FEV ₁ 25% - 50% of peak flow; or retractions present	cyanosis: FEV ₁ < 25% of peak flow or intubation necessary
Dyspnea	dyspnea on exertion	dyspnea with normal activity	dyspnea at rest	dyspnea requiring Oxygen therapy

GASTROINTESTINAL				
	Grade 1	Grade 2	Grade 3	Grade 4
Nausea	mild or transient; maintains reasonable intake	moderate discomfort; intake decreased significantly; some activity limited	no significant intake; requires IV fluids	hospitalization required;
Vomiting	1 episode in 24 hours	2-5 episodes in 24 hours	>6 episodes in 24 hours or needing IV fluids	physiologic consequences requiring hospitalization or requiring parenteral nutrition
Constipation	requiring stool softener or dietary modification	requiring laxatives	obstipation requiring manual evacuation or enema	obstruction or toxic megacolon
Diarrhea	mild or transient; 3-4 loose stools/day or mild diarrhea last < 1 week	moderate or persistent; 5-7 loose stools/day or diarrhea lasting >1 week	>7 loose stools/day or bloody diarrhea; or orthostatic hypotension or electrolyte imbalance or >2L IV fluids required	hypotensive shock or physiologic consequences requiring hospitalization

GASTROINTESTINAL (continued)

	Grade 1	Grade 2	Grade 3	Grade 4
Oral Discomfort/Dysphagia	mild discomfort; no difficulty swallowing	some limits on eating/drinking	eating/talking very limited; unable to swallow solid foods	unable to drink fluids; requires IV fluids

NEUROLOGICAL				
	Grade 1	Grade 2	Grade 3	Grade 4
Neuro-Cerebellar	slight incoordination dysdiadochokinesis	intention tremor, dysmetria, slurred speech; nystagmus	locomotor ataxia	incapacitated
Psychiatric	mild anxiety or depression	moderate anxiety or depression; therapy required; change in normal routine	severe mood changes requiring therapy; or suicidal ideation; or aggressive ideation	acute psychosis requiring hospitalization; or suicidal gesture/attempt or hallucinations
Muscle Strength	subjective weakness no objective symptoms/ signs	mild objective signs/symptoms no decrease in function	objective weakness function limited	paralysis
Paresthesia (burning, tingling, etc.)	mild discomfort; no treatment required	moderate discomfort; non-narcotic analgesia required	severe discomfort; or narcotic analgesia required with symptomatic improvement	incapacitating; or not responsive to narcotic analgesia

NEUROLOGICAL (continued)				
	Grade 1	Grade 2	Grade 3	Grade 4
Neuro-sensory	mild impairment in sensation (decreased sensation, e.g., vibratory, pinprick, hot/cold in great toes) in focal area or symmetrical distribution; or change in taste, smell, vision and/or hearing	moderate impairment (mod decreased sensation, e.g., vibratory, pinprick, hot/cold to ankles) and/or joint position or mild impairment that is not symmetrical	severe impairment (decreased or loss of sensation to knees or wrists) or loss of sensation of at least mod degree in multiple different body areas (i.e., upper and lower extremities)	sensory loss involves limbs and trunk; paralysis; or seizures

MUSCULOSKELETAL				
	Grade 1	Grade 2	Grade 3	Grade 4
Arthralgia (joint pain)	mild pain not interfering with function	moderate pain, analgesics and/or pain interfering with function but not with activities of daily living	severe pain; pain and/or analgesics interfering with activities of daily living	disabling pain
Arthritis	mild pain with inflammation, erythema or joint swelling – but not interfering with function	moderate pain with inflammation, erythema or joint swelling – interfering with function, but not with activities of daily living	severe pain with inflammation, erythema or joint swelling –and interfering with activities of daily living	permanent and/or disabling joint destruction
Myalgia	myalgia with no limitation of activity	muscle tenderness (at other than injection site) or with moderate impairment of activity	severe muscle tenderness with marked impairment of activity	frank myonecrosis

SKIN				
	Grade 1	Grade 2	Grade 3	Grade 4
Mucocutaneous	erythema; pruritus	diffuse, maculo papular rash, dry desquamation	vesiculation or moist desquamation or ulceration	exfoliative dermatitis, mucous membrane involvement or erythema, multiforme or suspected Stevens- Johnson or necrosis requiring surgery
Induration	< 15mm	15-30 mm	>30mm	
Erythema	< 15mm	15-30 mm	>30mm	
Edema	< 15mm	15-30 mm	>30mm	
Pruritus	slight itching at injection site	moderate itching at injection extremity	itching over entire body	

SYSTEMIC				
	Grade 1	Grade 2	Grade 3	Grade 4
Allergic Reaction	pruritus without rash	localized urticaria	generalized urticaria; angioedema	anaphylaxis
Headache	mild, no treatment required	transient, moderate; treatment required	severe; responds to initial narcotic therapy	intractable; requires repeated narcotic therapy
Fever: oral	37.7 - 38.5 C or 100.0 - 101.5 F	38.6 - 39.5 C or 101.6 - 102.9 F	39.6 - 40.5 C or 103 - 105 F	> 40 C or > 105 F
Fatigue	normal activity reduced < 48 hours	normal activity decreased 25- 50% > 48 hours	normal activity decreased > 50% can't work	unable to care for self

Appendix D: Supplement Table for Labs & Reference Ranges

The table reference below is to be used as a supplement to the DMID Adult Toxicity Table, November 2007, to adjust the laboratory values listed in DMID Toxicity Tables for Grading Adverse Events in this trial to be consistent with JHH lab normals. Laboratory values listed in this table will supersede the DMID table for toxicity grading of laboratory values. For some values there is a gap between the upper or lower limits for that value and grade 1 toxicity. Abnormal values which fall into this gap (for which the abnormality is too small to reach Grade 1 toxicity) will not be reported as AEs.

DMID 06-0091 Labs & Reference Ranges- JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
Sodium	135-148 mEq/L		HI	149-150 mEq/L	151-154 mEq/L	155-159 mEq/L	>160 mEq/L
			LO	130-134 mEq/L	125-129 mEq/L	121-124 mEq/L	<120 mEq/L
Potassium	3.5-5.1 mEq/L		HI	5.2-6.0 mEq/L	6.1-6.5 mEq/L	6.6-7.0 mEq/L	>7.0 mEq/L
			LO	3.0-3.4 mEq/L	2.5-2.9 mEq/L	2.0-2.4 mEq/L	<2.0 mEq/L
Chloride	96-109 mEq/L		HI	>112 mEq/L			
			LO	<93 mEq/L			

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
CO2	21-31 mEq/L		HI	>31.0 mEq/L			
			LO	16.0-20.9 mEq/L	11.0-15.9 mEq/L	8.0-10.9 mEq/L	<8.0 mEq/L L
Glucose (fasting)	60-99 mg/dL	56-115 mg/dL	HI	116-125 mg/dL	126-250 mg/dL	251-500 mg/dL	>500 mg/dL
			LO	41-59 mg/dL	31-40 mg/dL 1	21-30 mg/dL	0-20 mg/dL
BUN	7-22 mg/dL		HI	26-40 mg/dL	41-50 mg/dL	51-60 mg/dL	>60 mg/dL
			LO	No ADE IF <7 mg/dL			
Creatinine	Females: 0.5-1.2 mg/dL	0-1.3 mg/dL	HI	1.4-1.6 mg/dL	1.7-2.2 mg/dL	2.3-4.1 mg/dL	>4.1 mg/dL
	Males: 0.6-1.3 mg/dL	0-1.4 mg/dL	HI	1.5-1.7 mg/dL	1.8-2.3 mg/dL	2.4-4.4 mg/dL	>4.4 mg/dL

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
			LO *	NO AE IF <0.6 mg/dL			
Calcium	8.4-10.5 mg/dL		HI	10.6-11.5 mg/dL	11.6-12.5 mg/dL	12.6-13.5 mg/dL	>13.5 mg/dL
			LO	7.8-8.3 mg/dL	7.0-7.7 mg/dL	6.1-6.9 mg/dL	<6.1 mg/dL 1
Phosphate	2.7-4.5 mg/dL		HI	4.6-5.0 mg/dL	5.1-5.5 mg/dL	5.5-6.4 mg/dL	>6.5 mg/dL
			LO	2.7- 2.4 mg/dL 1	1.8-2.1 mg/dL 1	1.0-1.7 mg/dL	<1.00 mg/dL 1
Anion GAP	THIS IS A DERIVED NUMBER SO AE'S						

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
	DEFINED ON COMPONENT VALUES						
Liver Panel							
Alanine Amino Transferase (ALT).	Females: 0-31 U/L	0-41 U/L	*	42-78 U/L	79-155 U/L	156-310 U/L	>310 U/L
	Males: 0-40 U/L	0-49 U/L	*	50-100 U/L	101-200 U/L	201-400 U/L	>400 U/L
Alkaline Phosphatase	30-120 U/L	0-154 U/L	*	155-300 U/L	301-600 U/L	601-1200 U/L	>1200 U/L
Aspartate Amino Transferase (AST)	Females: <32 IU/L	0-45 IU/L	*	46-80 IU/L	81-160 IU/L	161-320 IU/L	>320 IU/L
	Males: <38 IU/L	0-47 IU/L	*	48-95 IU/L	96-190 IU/L	191-380 IU/L	>380 IU/L
Albumin, Serum	3.5-5.3 g/dL		**	3.0-3.4 g/dL	2.0-2.9 g/dL	<2.0 g/dL	NA
Gamma Glutamyl Transferase	Female: 8-51 IU/L	0-60 IU/L	*	61-128 IU/L	129-255 IU/L	256-1020 IU/L	>1021 IU/L
	Male: 12-55 IU/L	0-65 IU/L		66-139 IU/L	140-325 IU/L	326-1100 IU/L	>1100 IU/L
Lactic Dehydrogenase,	Females: 122-	0-220 U/L	*	221-550 U/L	551-1099 U/L	1100-2199 U/L	>2199 U/L

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
Serum	220 U/L						
	Males 118-273 U/L	0-273 U/L	*	274-683 IU/L	684-1364 IU/L	1365-2729 IU/L	>2729 IU/L
Total Protein	6.0-8.2 g/dL		HI	>8.3 g/dL			
			LO	<6.0 g/dL			
C3 Serum	79-152 mg/dL		**	<79 mg/dL			
C4 Serum	12-42 mg/dL		**	<12 mg/dL L			
CH-50, Serum	31 - 66 U/mL		**	10.00-30.99 U/mL	<10.00 U/mL		
Creatine Kinase (CK), Serum	Female: 24-170 IU/L	0-250 IU/L	*	510-1003 IU/L	1004-1699 IU/L	1700-3399 IU/L	>3399 IU/L
	Male: 24-195 IU/L	0-275 IU/L	*	585-1151 IU/L	1152-1949 IU/L	1950-3899 IU/L	>3899 IU/L
CK MB Isoenzyme	0-3%					>3% IU/L	
	0-7 IU/ml					>7 IU/ml	

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
Fibrinogen,Quantitative	150-450 mg/dL	120-460 mg/dL	**	100-119 mg/dL	75-99 mg/dL	50-74 mg/dL	<50 mg/dL
Haptoglobin	36-195 mg/dL	36-240 mg/dL	**	25-35 mg/dL	10-24 mg/dL	<10 mg/dL	—
Internation Normalized Ratio (INR)	INR: 0.9-1.1 Units		*	1.2-1.5 Units	1.6-2.0 Units	2.1-3.0 Units	>3.0 Units
APTT	22.4-29.5 seconds	20-30.6 seconds	*	30.7--45 seconds	46-65 seconds	66-100 seconds	>100 seconds
Kaolin Clotting Time	50-130 Units		*	>130 Units			
Heme-8:							
Hemoglobin (HGB)							
Female 18-21 g/dL	12.4-14.8 g/dL	11.5-16 g/dL	**	9.5—11.4 g/dL OR DECREASE BY 1.0-1.5 g/dL	8.0-9.4 g/dL OR DECREASE BY 1.6-2.5 g/dL	6.5-7.9 g/dL OR DECREASE BY 2.6-4.0 g/dL	<6.5 g/dL OR DECREASE BY >4.0 g/dL
Female >21 g/dL	13.9-16.3 g/dL	11.5-16 g/dL	**	9.5-11.4 g/dL OR DECREASE BY 1.0-1.5 g/dL	8.0 -9.4 g/dL OR DECREASE BY 1.6-2.5 g/dL	6.5-7.9 g/dL OR DECREASE BY 2.6-4.0 g/dL	<6.5 g/dL OR DECREASE BY >4.0 g/dL

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
Male 18-21 g/dL	13.2-15.6 g/dL	11.5-17.3 g/dL	**	9.5-11.4 g/dL OR DECREASE BY 1.0-1.5 g/dL	8.0-9.4 g/dL OR DECREASE BY 1.6-2.5 g/dL	6.5-7.9 g/dL OR DECREASE BY 2.6-4.0dL g/dL	<6.5 g/dL OR DECREASE BY >4.0 g/dL
Male>21 g/dL	13.9-16.3 g/dL	11.5-17.3 g/dL	**	9.5-11.4 g/dL OR DECREASE BY 1.0-1.5 g/dL	8.0-9.4 g/dL OR DECREASE BY 1.6-2.5 g/dL	6.5-7.9 g/dL OR DECREASE BY 2.6-4.0 g/dL	<6.5 g/dL OR DECREASE BY >4.0 g/dL
Hematocrit (Packed Cell Volume)	Female: 36.0-46.0%	GRADE THE SAME AS THE HEMOGLOBIN					
	Male: 41.0-53.0%	GRADE THE SAME AS THE HEMOGLOBIN					
Erythrocyte count (RBC)	Adult Female: 4.0 - 5.2 %	GRADE SAME AS HEMOGLOBIN					
	Adult Male: 4.5 - 5.9 %	GRADE SAME AS HEMOGLOBIN					
Erythrocyte count (RBC)	4.0-5.2 * X10 6/cu mm	GRADE SAME AS HEMOGLOBIN					
Leukocyte Count (WBC)							

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
18-21 YEARS	4500- 13000 cells/cu mm	3000-13,500 cells/cu mm	HI	>13,500 cells/cu mm			
18-21 YEARS	4500- 13000 cells/cu mm	3000-13,500 cells/cu mm	LO	2,000-2,500 cells/cu mm	1,500-1,999 cells/cu mm	1,000-1,499 cells/cu mm	<1,000 cells/cu mm
>21 YEARS			HI	>11,500 cells/cu mm			
>21 YEARS	4500 – 11000 cells/cu mm	3000-11,500 cells/cu mm	LO	2,000-2,500 cells/cu mm	1,500-1,999 cells/cu mm	1,000-1,499 cells/cu mm	<1,000 cells/cu mm
Differential %							
Neutrophils	40-70%			DEFER TO ABSOLUTE NUMBERS			
Immature Forms	0-1%			DEFER TO ABSOLUTE NUMBERS			
Lymphocytes	24-44%			DEFER TO ABSOLUTE NUMBERS			
Monocytes	2-11%			DEFER TO ABSOLUTE NUMBERS			
Eosinophils	1-4%			DEFER TO ABSOLUTE			

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
				NUMBERS			
Basophils	0-2%			DEFER TO ABSOLUTE NUMBERS			
Differential Counts							
Neutrophils	1500-7800 NUMBER/CU MM		HI	>7800 NUMBER/CU MM			
			LO	1000-1300 NUMBER/CU MM	750-999 NUMBER/CU MM	500-749 NUMBER/CU MM	<500 NUMBER/CU MM
Immature Forms	0-50 NUMBER/CU MM		*	51-365 NUMBER/CU MM	>365 NUMBER/CU MM		
Lymphocytes	1100-4800 NUMBER/CU MM		HI	6,000-7999 NUMBER/CU MM	8000-11,999 NUMBER/CU MM	12,000-20,000 NUMBER/CU MM	>20,000 NUMBER/CU MM
			LO	600-650 NUMBER/CU MM	500-599 NUMBER/CU MM	350-499 NUMBER/CU MM	<350 NUMBER/CU MM

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
Monocytes	100-1200 NUMBER/CU MM		*	>1200 NUMBER/CU MM			
Eosinophils	120-300 NUMBER/CU MM	90-300	*	301-599 NUMBER/CU MM	600-899 NUMBER/CU MM	900-3000 NUMBER/CU MM	>3000 NUMBER/CU MM
Basophils			*	>300 NUMBER/CU MM			
Nucleated RBC's	0 - 12 NUMBER/CU MM		*	13-30 NUMBER/CU MM	31-60 NUMBER/CU MM	61-120 NUMBER/CU MM	> 120 NUMBER/CU MM
Mean Corpuscular Hemoglobin (MCH),	26.0-34.0 pg/Cell		**	22.1-24.0 pg/Cell	20.1-22.0 pg/Cell	<20.1 pg/Cell	
MCHC	31.0-37.0 g/dL			DERIVED VALUES			
MCV							

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
Male	78.0-98.0 fL		HI	>98 fL			
			LO	<78 fL			
Female	80.0-100.0 fL		HI	>100 fL			
			LO	<80 fL			
RDW	11.5 - 14.5 %			DERIVED VALUES			
Platelets	150,000-350,000 cells/cu mm		HI	>351,000-450,000 cells/cu mm	>451,000-550,000 cells/cu mm	>550,000 cells/cu mm	
			LO	100,000-124,999 cells/cu mm	50,000-99,999 cells/cu mm	25,000-49,999 cells/cu mm	<25,000 cells/cu mm
Mean Platelet Volume (MPV)				DERIVED VALUE			
Reticulocyte Count %	0.5-1.8%			DERIVED. USE ABSOLUTE RETICS			
Reticulocyte Count (Absolute)	24,100-87,700 K/cu mm		*	>87,700 K/cu mm			

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
LDH Isoenzymes							
	LD-1: 26-45 IU/L		*	46-113 IU/L	114-225 IU/L	226-450 IU/L	>450 IU/L
	LD-2: 44-75 IU/L		*	45-188 IU/L	189-375 IU/L	376-750 IU/L	>750 IU/L
	LD-3: 20-41 IU/L		*	42-123 IU/L	124-205 IU/L	206-410 IU/L	>410 IU/L
	LD-4: 8-22 IU/L		*	23-55 IU/L	56-110 IU/L	111-220 IU/L	>220 IU/L
	LD-5: 6-29 IU/L		*	30-73 IU/L	74-145 IU/L	146-290 IU/L	>290 IU/L
Alkaline Phosphatase Isoenzyme							
Intestinal	1-24%		*	>24 %			
Bone	28-66%		HI	>67 %			
			LO	<28%			
Liver	25-69%		HI	>70 %			
			LO	<25%			
Urine Creatinine							
Males	40-278 mg/dL		*	279-556 mg/dL (2x uIN)	>556 mg/dL		
Females	29-226 mg/dL		*	227-452 mg/dL (2x ULN)	>452 mg/dL		

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Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
Urinalysis			***				
Urine Sodium (Spot)							
Females<40 years of age	15-267 mEq/L		HI!	>325			
Females>40 years of age	15-237 mEq/L		LO! !	<10			
Males<40 years of age	25-301 mEq/L		HI!	>235			
Males >40 years of age	18-214 mEq/L		LO! !	<10			
Specific gravity	1.003-1.030		HI	>1.030			
			LO	<1.003			
Protein	Negative-trace			1+	2-3+	4+	N/A
Hematuria	0-5 rbc/hpf		***	6-10 rbc/hpf	>10 RBC/HPF	Gross Blood or casts	Transfusion Indicated
ALL OTHER DIPSTICK ANALYTES	Negative		***	Positive			
Leukocytes	0-5 WBC			>5WBC/hpf			
Crystals (multiple types)	None			>1 Number/hpf			

DMID 06-0091 Labs & Reference Ranges-JHH Lab				DAIDS DEFINED SEVERITY GRADES FOR VALUES IN DAIDS CHART, OTHERWISE SEE CODES			
Test Name	Reference Range	APPENDIX B EXPANDED RANGES	HI-LO	GRADE 1	GRADE 2	GRADE 3	GRADE 4
	Number/hpf						
Granular Casts	None Number/hpf			>1 Number/hpf			
Hyaline Casts	None Number/hpf			>1 Number/hpf			