GENESIS ™ Veterinary Hematology System Customer Instruction

INTRODUCTION

The ***GENESIS*** Veterinary Hematology System is a quantitative, automated hematology analyzer for veterinary in-clinical and research laboratories. The ***GENESIS*** is intended for determining a variety of hematologic parameters on peripheral blood, including:

WBC: White Blood Cell or leukocyte count
NE#: Neutrophil count
NE%: Neutrophil percent
LY#: Lymphocyte count
LY%: Lymphocyte percent
MO#: Monocyte count
MO%: Monocyte percent
EO#: Eosinophil count
EO%: Eosinophil percent
BA#: Basophil count
BA%: Basophil percent
NRBC#: Nucleated Red Blood Cell count
NRBC%: Nucleated Red Blood Cell percent
HCT: Hematocrit or relative volume of erythrocytes

RBC: Red Blood Cell or erythrocyte count
Hb: Hemoglobin concentration
MCV: Mean Corpuscular (erythrocyte) Volume
MCH: Mean Corpuscular (erythrocyte) Hemoglobin
MCHC: Mean Corpuscular (erythrocyte) Hemoglobin Concentration
RDW: Red Cell (erythrocyte volume) Distribution Width
RSD: Red Cell (erythrocyte volume) Standard Distribution
Retics#: Reticulocyte count
Retics%: Reticulocyte percent

PLT: Platelet or thrombocyte count
PCT: Platelet (Hemato) Crit
MPV: Mean Platelet Volume
PDW: Platelet Distribution Width

The purpose of the ***GENESIS*** analyzer is to accurately determine values for hematologic parameters in order to distinguish between normal patients and those who need additional study of any of these parameters. These additional studies usually include examining the blood smear to evaluate RBC, WBC and Platelet morphology and differential and may also include biochemical investigation. The ***GENESIS*** is designed to automatically flag for hematologic abnormalities.

OPERATING RANGE LINEARITY LIMITS

When tested using dilutions made from a sample having no interfering substances, the ***GENESIS*** Hematology System's value will be equal to the expected value within the limits given in **table below**. To obtain the same results, multiple readings must be taken at each point in order to eliminate the statistical effects of imprecision. Linearity of size measurements (e.g. MCV) are tested using appropriate techniques.

Parameter	**Linearity Range**	**Limits** *(whichever is greater)*
WBC x 10^3 cells/mm^3 ($x10^9$/L)	0.0 to 125.0	+/- 3.0 or 5.0%
RBC x 10^6 cells/mm^3($x10^9$/L)	0.00 to 20.00	+/- 0.05 or 5.0%
Hb g/dL	0.0 to 34.0	+/- 0.2 or 3.0%
MCV fL	30 to 300	+/- 1.5 or 2.0%
PLT x 10^3 cells/mm^3($x10^9$/L)	0 to 5000	+/- 10 or 10%

BLOOD SPECIMEN COLLECTION AND HANDLING

Specific material need for *GENESIS* Veterinary Hematology Analyzer

1. The only accept anticoagulant for ***GENESIS*** system is K3 EDTA (tripotassium ehtylenediaminetetraacetic acid). ***The use of heparin or citrate as anticoagulant may cause a bias in WBC, Hb, and Differential readings.***
2. For K3 EDTA Vet-Set blood collection tubes, please contact SKCC Translational Research / Pathology Shared Resource before you plan to collect blood samples.

For the best result, always try to fill the EDTA (purple/lavender top) tube at least 50% full (~100 ul, minimum acceptable volume is 50ul). If you have a short draw (less than 50%), the sample can still be processed (***GENESIS*** will only bring 20 ul undiluted sample into the instrument). Keep in mind that the sample will be diluted by excess K3 EDTA (~5ul of K3 EDTA is measured in Vet-Set blood collection tubes) when you have a limited volume of blood samples, which could cause the values to be lower and the cells may be crenated, causing the cell size to be smaller. Collect enough and about the same volume of sample could minimize the variation caused by dilution factor between samples.

Collect and prepare the specimen as bellow:

1. Label the tube with preferred ID of your animal. Please minimize number of characters to reduce our technician time to type into the analyzer.
2. Collect the specimen by venipuncture and use tripotassium ehtylenediaminetetraacetic acid (K3 EDTA) as the anticoagulant. For detailed information on the collection of the whole blood by ventipuncture, refer to Institutional Animal Care and Use Committee (IACUC) guideline of your institute.
3. Mix the blood specimen with the K3 EDTA carefully, and thoroughly as follows:
   - Place the specimen on a tube rocker/rotator (set the speed at ~25rpm) for a minimum of five minutes.
   - Remove the specimen from rocker/rotator and gently invert the tube three (3) times.

SPECIMEN STORAGE

Since blood platelets (PLT) disintegrate rapidly, whole-blood cell counts that include PLT should be performed within 4 hours after drawing (Cat specimen within 20 minutes) for optimum results. Whole-blood cell counts that **do not need PLT** could be performed within 24 hours after drawing. Whole-blood specimens for PLT and differential counts must be run at room temperature. Samples stored in 4˚C must be brought to room temperature for 15 minutes before load into the instrument.

SMEAR SLIDES PREPARATION

For the diagnosis of hematologic disorders and backup plan in case the instrument failure, you might need microscopic observation of cell morphology in peripheral blood smears. It is recommended that prepare blood smears within a few hours after the samples drawing and perform.

SUBMIT BLOOD SAMPLE TO THE SHARED RESOURCE

You need create an online requisition via iLab system in advance. Print out request form and submit the form together with blood samples to this shared resource. Please note that each test will take about 3-5 minutes. Sample submitted in late afternoon might be analyzed the next day. So, **plan your experiment carefully if you want the sample to be analyzed the same day and avoid submit sample in late afternoon of Friday**.

TEST SESULTS RETENTION AND ACQUISITION

Users are responsible to keep their test records. The ***GENESIS*** system will generate a hard copy of the test result as well as an electronic copy (Excel file). You can come to the shared resource to pick up the hard copy once you are acknowledged that the test is completed. The electronic copy (Excel file) will be sent to users via email as well. Please note that the ***GENESIS*** system could store up to 2000 test results. The extra result will be erased automatically base on the order of testing time.

LEFT OVERBLOOD SAMPLES

The leftover blood samples will be discarded as biohazardous waste. Please notify the shared resources in case you need us to keep the leftover blood samples for other purpose.

DATA INTERPRETATION

GENESIS **Parameter Table** (lists the parameters reported by the ***GENESIS***, their definitions, the international units of measure, the ***GENESIS*** units of measure, and the formulas for equivalent unit conversion)

PARAMETERS	DEFINITION	*GENESIS* ANALYZER UNIT OF MEASURE	EQUIVALENT UNIT CONVERSION
1. WBC: *White Blood Cell (leukocyte)Count*	Number of leukocytes in the specified volume of whole blood. Directly Measured.	Thousands of leukocytes per microliter of whole blood: K/µL	10^9 /Liter = 10^3 /µL = K/µL
2. NE #	Absolute number of leukocytes that are neutrophils. Directly measured.	Thousands of neutrophils per microliter of blood: K/µL	10^9 /Liter = 10^3/µL = K/µL
3. NE %	Percent of leukocytes that are neutrophils.	Percent %	None
4. LY #	Absolute number of leukocytes that are lymphocytes. Directly measured.	Thousands of lymphocytes per microliter of blood: K/µL	10^9 /Liter = 10^3/µL = K/µL
5. LY %	Percent of leukocytes that are lymphocytes.	Percent %	None
6. MO #	Absolute number of leukocytes that are monocytes. Directly measured.	Thousands of monocytes per microliter of blood: K/µL	10^9 /Liter = 10^3/µL = K/µL
7. MO %	Percent of leukocytes that are monocytes.	Percent %	None
8. EO #	Absolute number of leukocytes that are eosinophils. Directly measured.	Thousands of eosinophils per microliter of blood: K/µL	10^9 /Liter = 10^3/µL = K/µL
9. EO %	Percent of leukocytes that are eosinophils.	Percent %	None
10. BA #	Absolute number of leukocytes that are basophils. Directly measured.	Thousands of basophils per microliter of blood: K/µL	10^9 /Liter = 10^3/µL = K/µL
11. BA %	Percent of leukocytes that are basophils.	Percent %	None
12. NRBC#	Absolute number of erythrocytes that are immature nucleated red blood cells. Directly measured and flagged.	Thousands of NRBC's per microliter of blood: K/µL	10^9 /Liter = 10^3/µL = K/µL
13. NRBC %	Percent of erythrocytes that are nucleated red blood cells flagged.	Percent %	None
14. HCT: *Hematocrit*	Relative volume of erythrocytes. Computed from RBC and MCV: (RBC X MCV) ÷ 10	Percent: %	L/L = % 100
15. RBC: *Red Blood Cell (erythrocyte) count*	Number of erythrocytes in the specified volume of whole blood. Directly Measured.	Millions of erythrocytes per microliter of whole blood: M/µL	10^{12}/Liter = 10^6/µL = M/µL
16. Hb: *Hemoglobin*	Mass or weight of hemoglobin in the specified volume of whole blood. Directly measured.	Grams of hemoglobin per deciliter of whole blood: g/dL	g/L = g/dL x 10
17. MCV: *Mean Corpuscular(erythrocyte)Volume*	Average volume of individual erythrocytes in whole blood. Directly measured.	Femtoliter: fL or 10-15 liter	fL = μ^3

PARAMETER	DEFINITION	*GENESIS* NALYZER UNIT OF MEASURE	EQUIVALENT UNIT CONVERSION
18. MCH: *Mean Corpuscular (erythrocyte) Hemoglobin*	Mass or weight of hemoglobin in the average individual erythrocyte. Compute from Hb and RBC: 10 x (Hb ÷ RBC)	Picograms of hemoglobin per erythrocyte: pg or 10-12g	None
19. MCHC: *Mean Corpuscular (erythrocyte) Hemoglobin (Concentration)*	Average mass or weight of hemoglobin in specified volume of erythrocytes. Computed from Hb and Hct: 100 x (Hb ÷ Hct)	Grams of hemoglobin per deciliter of erythrocytes: g/dL	g/L = g/dL x 10
20. RDW: *Red Cell (erythrocyte volume) Distribution Width*	The size-distribution spread of the erythrocyte population expressed as the coefficient of variation of the red cell distribution.	Percent %	None
21. RSD: *Red Cell (erythrocyte) standard Deviation*	The size-distribution spread of the erythrocyte population expressed as the standard deviation of the red cell distribution. Directly measured	Femtoliter: fL or 10-15 liter	fL = μ^3
22. RETICS #: *(Reticulocytes)*	Number of immature nonnucleated erythrocytes in the specified volume of whole blood. Directly measured and flagged	Millions of reticulocytes per microliter of whole blood: M/µL	10^{12} /Liter = 10^6 /µL = K/µL
23. RETICS %: *(Reticulocytes)*	Percent of immature nonnucleated erythrocytes in the specified volume of whole blood flagged.	Percent %	None
24. PLT: *Platelet (thrombocyte) Count*	Number of platelets (thrombocytes) in the specified volume of whole blood. Directly measured.	Thousands of thrombocytes per microliter of whole blood: K/µL	10^9 /Liter = 10^3 /µL = K/µL
25. PCT: *Plateletcrit*	Relative volume of platelets (thrombocytes). Computed from PLT and MPV: (PLT x MPV) ÷ 10	Percent %	L/L = % 100
26. MPV: *Mean Platelet (thrombocyte) Volume*	Average volume of individual platelets (thrombocytes) in whole blood. Directly measured.	Femtoliter: fL or 10-15 liter	fL = μ^3
27. PDW: *Platelet (thrombocyte volume) Distribution Width*	The size distribution spread of the platelet (thrombocyte) population expressed as the coefficient of variation of the platelet distribution	Percent %	None

Leukocyte Differential: The ***GENESIS*** analyzer generates a WBC differential by constructing a distribution cytogram based on the relative size (impedance) and complexity (light scatter) of cells in a blood sample. Each cell passing through

the instrument's sensing zone is analyzed, compared to known criteria, and placed in a corresponding area in the cytogram, based on these criteria. For example, a cell with the size and internal complexity of neutrophils is placed in the neutrophil "area" in the cytogram. Percentages and absolute cell numbers are then calculated.

Thrombocyte/Erythrocyte Analysis: Platelet and erythrocyte enumeration is accomplished in much the same way as the WBC count and differential. Cells passing through the instrument are analyzed, placed in a corresponding area in the cytogram, and compared to known criteria for identification.

Messages: Certain conditions cell distributions trigger the following messages to alert the operator that abnormal conditions may exist.

Note: Message appears in the DIAGNOSTIC CONSIDERATIONS section of the report form to clarify these conditions.

The following suspect message may appear adjacent to the leukocyte, erythrocyte, or thrombocyte parameters.

L: Indicated that the number or percentage is below the present normal range.

H: Indicates that the number or percentage is above the preset normal range.

If a particular leukocyte, erythrocyte or thrombocyte parameter is above the instrument's linearity limit, the word "HIGH" will appear in place of a numeric result. See diluted sample below.

If an error occurs in the calculation of a particular leukocyte, erythrocyte or thrombocyte parameter, dashes (----) will appear in place of the numeric result.

Diluted Samples: When the WBC, RBC, Hb, or PLT parameters are above the instrument's linearity limit, meaningful results may still be obtained by rerunning a diluted sample and multiplying the results by an appropriate factor. For example, equal parts of specimen and dilution can be mixed for a 1:2 dilution and the printed results multiplied by 2 to obtain the actual values. This technique applies only to WBC, RBC, Hb and PLT parameters. The remaining parameters must be verified by other methods (e.g., Reference Methods).

Raw Input Data and Calculation Errors: The ***GENESIS*** alerts errors in raw input data or calculation errors. A blank on the printed report for any parameter indicates that the ***GENESIS*** detected an error in raw input data with respect to that parameter. A series of dashes (----) on the printed report for any parameter indicates that a calculation error occurred with respect to that parameter.