

DREW Scientific Inc.

Directions for **MULTI-TROL™**

I. **INTENDED USE.** MULTI-TROL™ is a stabilized reference control system designed to monitor the accuracy and precision of hematology instruments used to determine the parameters that are routinely included when analyzing multiple species of animals.

II. **SUMMARY AND PRINCIPLES.** Since the size, quantity, and physiology of blood cells vary greatly from one species to another, the ability of hematology instruments to detect these differences should be closely monitored. The use of blood cell quality control material to monitor the accuracy and precision of methods used to determine the parameters routinely included in complete blood counts is an established procedure. The MULTI-TROL™ from DREW Scientific closely resembles blood cells from a variety of animal species, and as such, they can be used to control a variety of procedures. These controls are stabilized suspensions of blood cells assayed for techniques and instruments which perform:

WBC	leukocytes count
RBC	erythrocytes count
Hb	hemoglobin concentration
Hct	relative volume of erythrocytes
MCV	mean corpuscular volume
MCH	mean corpuscular hemoglobin
MCHC	mean corpuscular hemoglobin concentration
RDW	red cell distribution width
PLT	platelets count
MPV	mean platelet volume
LY#	lymphocyte number
LY%	lymphocyte percent

Assayed values are specific to each lot. The values are assigned from results obtained with a number of automated instruments using statistical protocols established by DREW Scientific. Laboratories using instruments or methods other than those listed on the reverse side of this sheet should establish their own values. Values for analyses performed daily should be plotted graphically, and the mean values, standard deviations and coefficients of variation should be calculated to show the precision limits of each procedure.

III. **PRECAUTIONS.** Potential biohazard. May contain human source material. Treat as potentially infectious.

IV. **STORAGE AND STABILITY.** MULTI-TROL™ MUST BE KEPT COLD. Refrigerate at a temperature between 2° and 8° C (35° - 46° F). MULTI-TROL™ stored at this temperature range is guaranteed to be stable until the expiration date. DO NOT FREEZE OR LEAVE AT ROOM TEMPERATURE. To insure against changes in assay values, proper care must be taken after vials are opened. Opened vials of controls should not be used for periods exceeding 14 days. Evaporation or contamination may produce changes in the assay values. Any unused open-vial material should be discarded after 14 days. When instructions for storage and use of this product are followed, the laboratory's mean should fall within the published expected range.

Inability to obtain expected values may indicate product instability or deterioration. Discoloration of the product may occur if exposed to extreme temperatures during shipping. Gross hemolysis (darkly colored supernatant) may indicate deterioration. If MULTI-TROL™ values are not within expected ranges,

1. Review operating procedures of instrument in Reference Manual, and
2. Assay an unopened vial using reference methods. If values are still outside expected ranges, call DREW Scientific Customer Support, (800) 858- 7331.

V. **PROCEDURE.** MULTI-TROL™ should be treated exactly as a patient specimen:

1. Remove only the necessary number of vials from refrigerator.
2. Allow the vial to stand at room temperature for approximately 15 minutes.
3. To mix contents thoroughly, roll the vial gently between the palms of the hands 12 times. Change the vial position from vertical to horizontal and roll the vial gently 12 more times. Change positions and repeat twice more.
4. After mixing, use the vial in the same manner as a fresh whole blood sample.

VI. **PERFORMANCE CHARACTERISTICS.** Accuracy is achieved by careful whole blood calibration of instruments using recommended procedures. Precision of results is reflected by the acceptable ranges listed on the reverse side. The ranges given for the indices may fall outside the listed ranges. The mean values listed on the reverse side represent the consequences of data taken using several instruments with a minimum of 20 determinations. An instrument may be considered to be functioning properly if at least 95% of all results obtained with the controls are within the listed acceptable ranges. When three or more consecutive measurements for a given parameter are outside the listed acceptable range, it may indicate that the instrument is not operating properly or that the control has altered from its original condition.

If this situation is observed, the instrument calibration should NOT be changed until you,

1. Repeat daily operational checks and review recommended procedures found in your operator's manual, AND
2. Clean the instrument and check all hardware fluidics lines and reagents, making sure they are operating correctly.