

ASSAY VALUES AND EXPECTED RANGES

LOT / LOT N°: **PT051**

VALEURS CIBLES ET INTERVALLE DE VARIATIONS

EXP. DATE: **2011-10-31**

UNITS / UNITES × 10 ³ /μL	LOW ABNORMAL / ANORMAL BAS		NORMAL / NORMAL		HIGH ABNORMAL / ANORMAL HAUT	
	LOT NO	PT051L	LOT NO	PT051N	LOT NO	PT051H
	MEAN	RANGE	MEAN	RANGE	MEAN	RANGE
COULTER F, FN AND Z SERIES	36	24 - 48	328	288 - 368	500	430 - 570
SEMI-AUTOMATED AND MANUAL	31	19 - 43	310	260 - 360	483	413 - 553

INTENDED USE

Platelet-o-trol II is a control for use in monitoring values obtained from hematology instruments that provide platelet parameter determinations. Refer to the assay table for specific instrument models.

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials which provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

REAGENTS

Platelet-o-trol II is an *in vitro* diagnostic reagent composed of mammalian platelets suspended in a plasma-like fluid with preservatives.



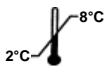
PRECAUTION

Platelet-o-trol II is intended for *in vitro* diagnostic use only by trained personnel.



WARNING

POTENTIAL BIOHAZARDOUS MATERIAL. Wear protective laboratory gloves and other blood barrier protection when handling this control. Human Blood components were not used in the manufacture of this control. However, this control does contain components from non-human sources and may transmit infectious disease. When handling or disposing of product, follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (OSHA 29 CFR Part 1910.1030) or other equivalent biosafety procedures.



STABILITY AND STORAGE

Store **Platelet-o-trol II** upright at 2 - 8° C when not in use. **Protect tubes from overheating and freezing.** Unopened tubes are stable through the expiration date. Opened tubes are stable for 14 days, provided they are handled properly.

INDICATIONS OF DETERIORATION

Product should be light tan and slightly cloudy. Discoloration of the vials may indicate deterioration or contamination. **Do not use the product if deterioration is suspected.**



INSTRUCTIONS FOR USE

1. Remove tubes from the refrigerator and allow to warm to room temperature (15 - 30° C or 59 - 86° F) for 15 minutes before mixing.
2. Before using a tube for the first time, use a vortex mixer and vigorously agitate the tube for 2 minutes to insure complete dispersion of microaggregates. Further sampling requires only a 30 second vortexing.
3. Let sample sit undisturbed for 10 minutes to allow micro bubbles to dissipate before sampling.
4. Examine the tube before sampling to be sure no debris or large aggregates are visible.
5. Gently invert the tube 10 times immediately before sampling. Analyze the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
6. After sampling:

- a) If tube has been open for sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
- b) Return tubes to refrigerator within 30 minutes of use.

EXPECTED RESULTS

Verify that the lot number on the tube matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer's recommended reagents. Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.

PERFORMANCE CHARACTERISTICS

Assigned values are presented as a Mean and Range. The Mean is derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material.

Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range.

For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not listed on the Assay Sheet, if the control is suitable for the method.

LIMITATIONS

The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control recovery problems, please call Technical Service at (02551) 4090. For additional information on BGT GmbH hematology controls and calibrators, or to place an order, call Customer Service at (02551) 4090.

QUALITY CONTROL PROGRAM

For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (02551) 4090. All brands and products are trademarks or registered trademarks of their respective companies.

Aktuelle Werteblätter zu den Chargen von **Platlet-o-trol II** finden Sie im Internet unter **www.werteblatt.de**