

LOT 121



2012-02-05

ASSAY VALUES AND EXPECTED RANGES

Units x 10 ³ /μL	LEVEL 3		LEVEL 4		LEVEL 5		LEVEL 6		LEVEL 7	
	LOT	1213	LOT	1214	LOT	1215	LOT	1216	LOT	1217
Instrument:	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range
ABBOTT CELL-DYN [®] Sapphire	950	840-1060	NA		1600	1440-1760	2575	2325-2825	NA	
ABBOTT CELL-DYN 3500 CELL-DYN 3700	1050	940-1160	1400	1250-1550	1805	1605-2005	NA		NA	
ABBOTT CELL-DYN 3500 CELL DYN 3700/VET mode*	1050	940-1160	NA		1805	1605-2005	2975	2675-3275	NA	
ABX Micros 60	1190	1040-1340	NA		2015	1785-2245	3200	2880-3520	NA	
ABX Pentra 80 Software Rev. 1.9.0	1130	980-1280	1480	1300-1600	1860	1590-2130	NA		NA	
Bayer ADVIA [®] 120	1110	960-1260	1535	1385-1685	1950	1700-2200	3180	2860-3500	NA	
BECKMAN COULTER [®] LH 700 Series	1040	930-1150	1390	1240-1540	1810	1630-1990	3060	2780-3340	NA	
Sysmex XE-2100	920	810-1030	1250	1100-1400	1630	1450-1810	2700	2380-3020	4800	4200-5400
Sysmex XE-2100D	1075	965-1185	1380	1230-1530	1800	1620-1980	3050	2730-3370	5420	4820-6020

Note: Assay means and range values may exceed manufacturer's linearity claims. Linearity must be verified by the user.

*The VET mode on the CD3500 and CD3700 instrument is not a FDA approved method.

INTENDED USE

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



PRECAUTION

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

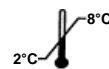


WARNING

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 Extended** 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.

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Platelet-o-trol Extended finden Sie im Internet
unter**

www.werteblatt.de