

PLATELET-TROL Extended

HEMATOLOGY CONTROLS

CONTROL

LOT

PTE0624



2024-08-05

ASSAY VALUES AND EXPECTED RANGES

Units x 10 ³ /μL	LEVEL 3		LEVEL 4		LEVEL 5		LEVEL 6	
	LOT	PTE0624-3	LOT	PTE0624-4	LOT	PTE0624-5	LOT	PTE0624-6
Instrument:	Mean	Range	Mean	Range	Mean	Range	Mean	Range
ABBOTT CELL-DYN® Sapphire	1075	880 – 1270	NA		1975	1615 – 2335	2595	2125 - 3065
ABX Micros 60	1295	1070 – 1520	NA		2340	1985 – 2695	3030	2545 - 3515
Bayer ADVIA® 120	1235	1110 – 1360	NA		2350	1995 – 2705	3165	2750 – 3580
ABX Pentra80, Pentra 80XL, Pentra 80XLR	1195	990 – 1400	1645	1380 – 1910	2150	1720 – 2580	NA	

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

INTENDED USE

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



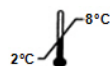
PRECAUTION

PLATELET-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-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.**

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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, vortex the sample on a vortexer for 2 minutes making sure a vortex is created in the tube. 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 (800) 523-3395. For additional information on R&D Systems, Inc. hematology controls and calibrators, or to place an order, call Customer Service at (800) 428-4246.

QUALITY CONTROL PROGRAM

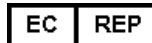
For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (800) 523-3395 ext. 4435.

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AIS103-023 Rev. 03/23



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