

REF 6603473

PN 4235777-N



For In Vitro Diagnostic Use

Intended for use as a flow cytometry quality control reagent for determining instrument linearity and for standardization of fluorescence intensity.

SUMMARY

The EPICS™ IMMUNO-BRITE™ Standards Kit (PN 6603473) is composed of five vials. Each vial contains particles of a specific fluorescent intensity: Blank, Med-Low, Reference-Med, Med-Hi, and Brite. Each vial has a 10-mL suspension of particles at a concentration of 1×10^6 /mL in aqueous dispersant plus preservative. These particles are composed of polystyrene and a fluorescent dye. The fluorescent dye emits from 525 to 700 nm at an excitation of 488 nm. The kit is used for verification of instrument log amplifier linearity.

REAGENTS

- Particles, 10 mL at 1×10^6 /mL
- Level I (Blank)
- Level II (Med-Low)
- Level III (Reference-Med)
- Level IV (Med-Hi)
- Level V (Brite)

INSTRUCTIONS FOR USE

Verification of linearity of the instrument is essential to ensure that the low-intensity signals and high-intensity signals are amplified at the same ratio.

1. Optically align the flow cytometer with Flow-Check™ (PN 6605359) alignment fluorospheres.
2. Dispense 0.5 mL IMMUNO-BRITE Standard from the Level III bottle into a sample tube.
3. Acquire a histogram of forward scatter versus side scatter at a count rate of 100 to 500 particles/s. Acquire histograms of log fluorescence from each fluorescence PMT. Gate these histograms on the main population of the scatter histogram to eliminate doublets and background from the analysis. Adjust PMT voltages to level desired for testing. Position of peaks representing fluorescent and blank spheres will vary within the histogram depending on the voltages used. At least three peaks must appear on scale for linearity calculation.
4. Save PMT voltage changes on instrument protocol.
5. Dispense 0.5 mL from each of the five IMMUNO-BRITE bottles (Levels I through V) into a sample tube and run on the protocol as determined in step 3.
6. Analyze each fluorescence histogram. Place cursors around each fluorescence peak and record mean channel values.
7. Graph the mean channel values as obtained above against relative separation for each Level on the graph paper provided.
8. Connect the four points representing the particles from Levels II through V. The resulting line should be approximately straight. If not, repeat this procedure. If

you still do not get a straight line, the instrument needs recalibration by a Beckman Coulter Service Representative.

REAGENT STORAGE AND STABILITY

Store at 2-8°C when not in use. Unopened vials can be expected to remain stable until the expiration date stamped on the package label when stored at 2-8°C.

Inability to obtain expected results may indicate need to refer to instrument troubleshooting guide. Particle suspensions should not be allowed to dry out. Discard previously prepared samples. Prepare a new sample each time an analysis is performed. Samples that exhibit doublets should be sonicated lightly in an ultrasonic bath until the doublets are removed.

REFERENCES

1. Perfetto S, Ross W, Riley R, Mahin E. Quality Assurance and Quality Control in Flow Cytometry. Clinical Applications of Flow Cytometry. 1993. p. 867-868.
2. Riley R, Ross W, Perfetto S. Setting up a Flow Cytometry Laboratory. Flow Cytometry and Clinical Diagnosis. 1994. p. 163-164.

TRADEMARKS

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For additional information, or if damaged product is received, call Beckman Coulter Customer Service at 800-526-7694 (USA or Canada) or contact your local Beckman Coulter Representative.

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Printed in USA
Made in USA

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**TO AVOID CONTAMINATION AND DEGRADATION
DO NOT ASPIRATE REAGENT DIRECTLY FROM
THE BOTTLE.**

IMMUNO-BRITE STANDARDS KIT

Log Amplifier Linearity Verification

Use this page for log channels numbered 1 to 255 OR 1 to 1023

IMMUNO-BRITE STANDARD												
LEVEL V												
LEVEL IV												
LEVEL III												
LEVEL II												
	0	40 160	80 320	120 480	160 640	200 800	240 960	255 1023				
	MEAN LOG CHANNEL NUMBER											

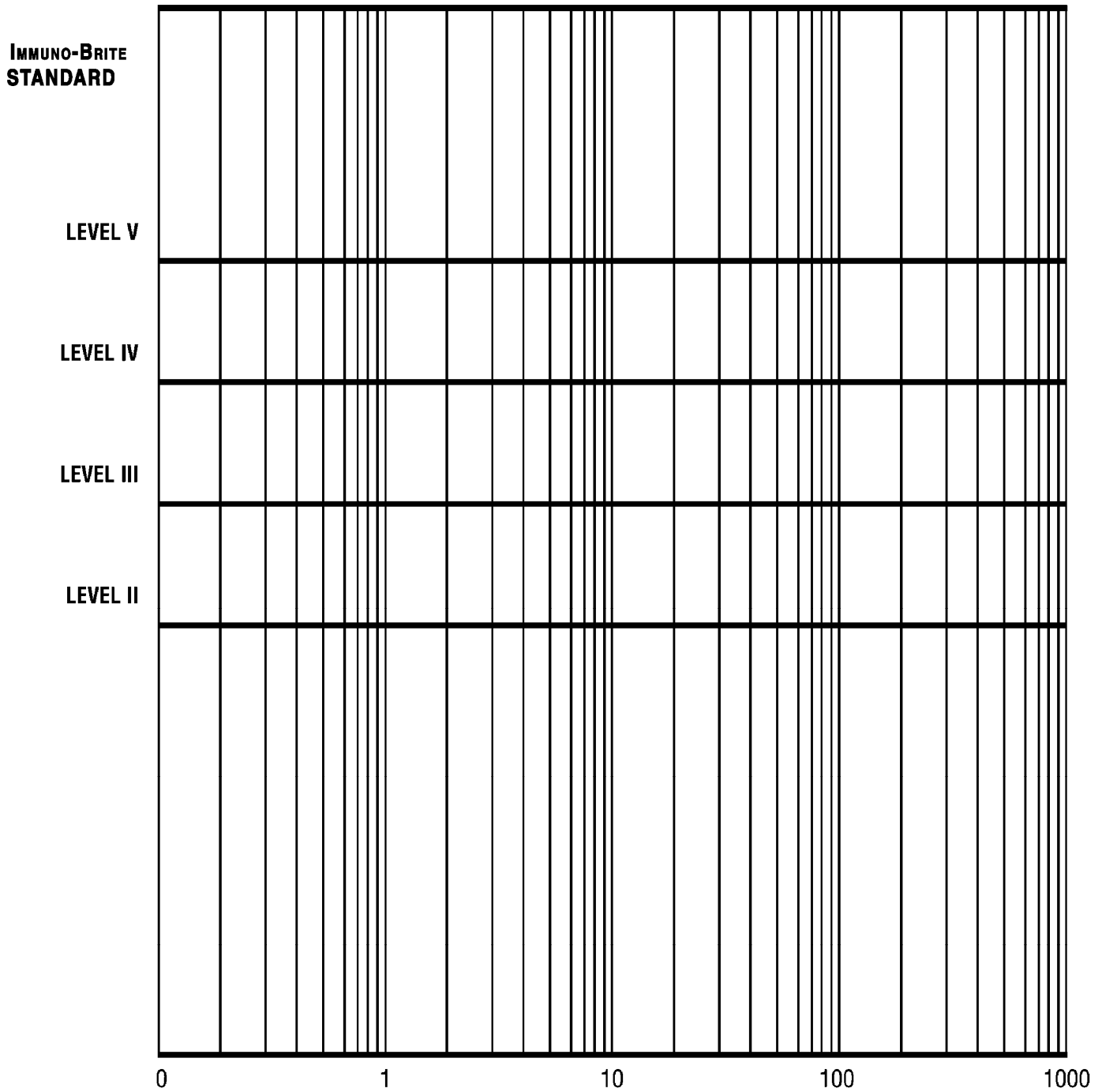
Month: _____ Year: _____ Lot Number _____

Expiration Date _____ / _____ / _____

IMMUNO-BRITE STANDARDS KIT

Log Amplifier Linearity Verification

Use this page for log channels numbered 0.1 or 1 to 1000



MEAN LOG CHANNEL NUMBER/

Month: _____ Year: _____ Lot Number _____

Expiration Date _____/_____/_____