

Trillium Diagnostics, LLC *** Leuko64 Assay

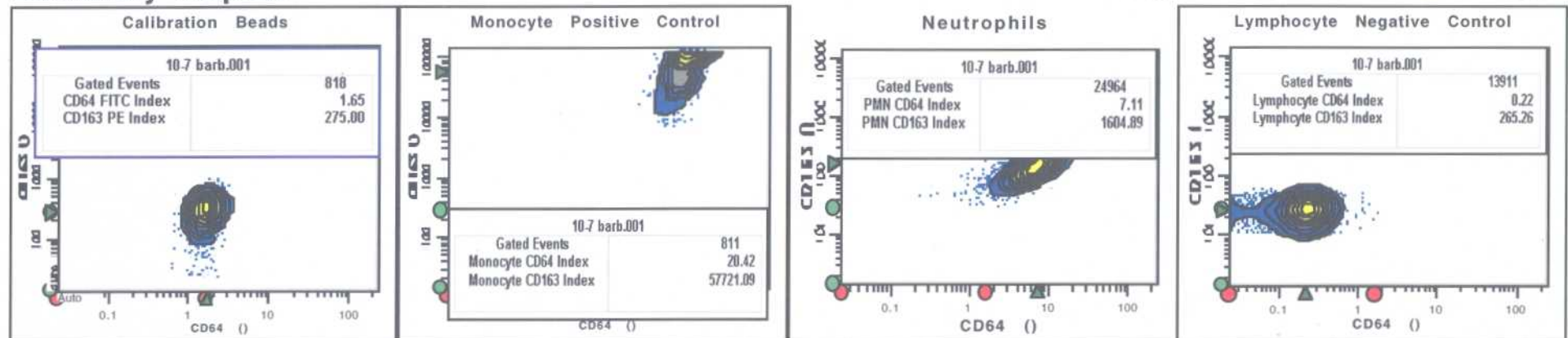
Neutrophil CD64 Measurements are for in vitro diagnostic use in EU countries and research use only in North America.

Leuko64 Lot #LK08-01

Expiration: 31 December 2010

Summary Report

Date: 11Feb2011 Time: 14:43:52



Analysis of Leukocyte CD64 Expression. Normal PMN CD64 expression is low with a PMN CD64 Index of <1.0 in healthy donors or <2.0 in hospitalized populations (reference ranges should be verified for each laboratory). The PMN CD64 Index increases (typically >3.0) during a systemic acute inflammatory response to tissue injury, such as occurs with infection or sepsis. The upregulation of CD64 occurs under the influence of inflammatory cytokines, such as G-CSF and interferon-gamma. The Leuko64 assay performs simultaneous analysis of CD64 expression on lymphocytes (no expression, CD64 index <1.00), monocytes (moderate to high expression, CD64 Index >3.00), and neutrophils (variable expression, but low in the healthy state).

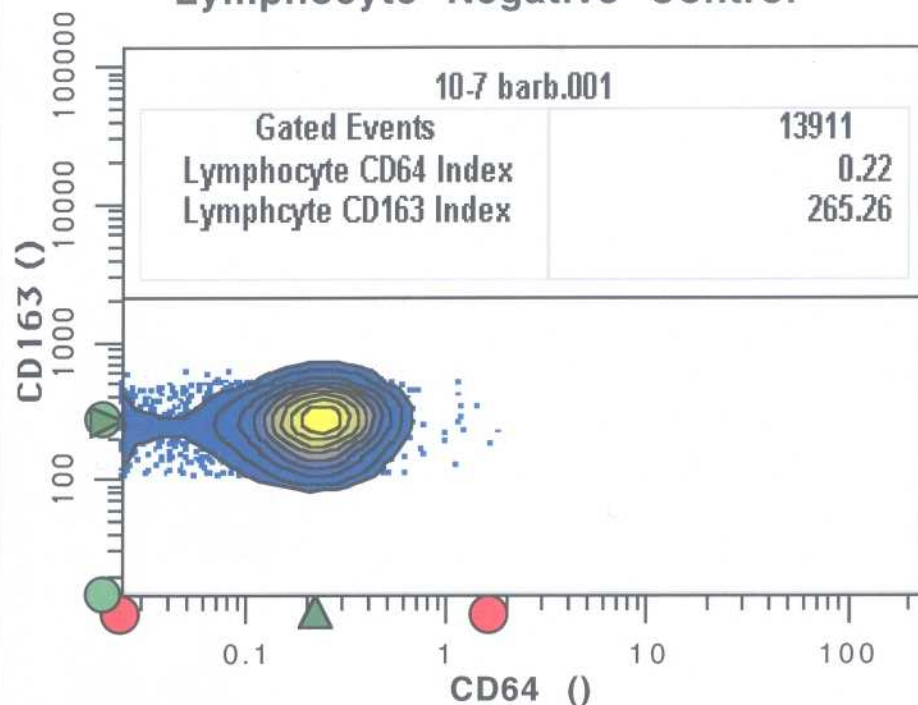
Results of the PMN CD64 Index should be reported only when both the negative control (lymphocyte CD64 Index) and positive control (monocyte CD64 Index) values are within the appropriate ranges. If these control conditions are not met, specimen staining and analysis should be repeated prior to reporting the PMN CD64 Index values.

Reviewed by: _____

Date: _____

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Lymphocyte Negative Control

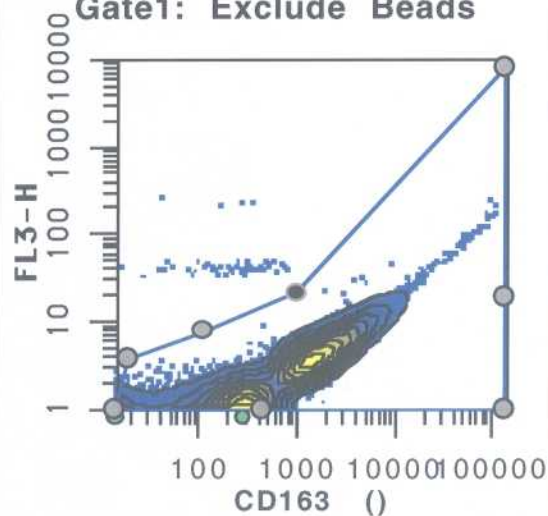


10-7 barb.001

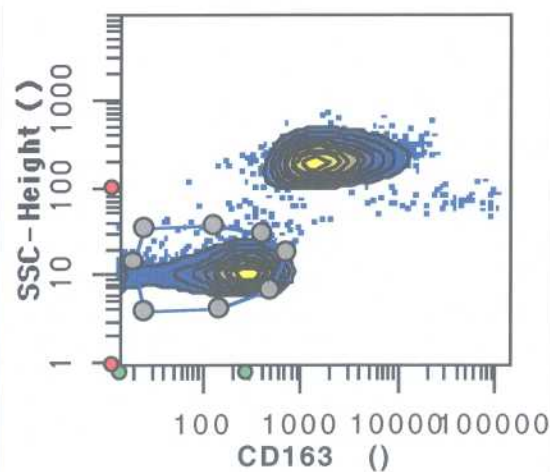
Gated Events	13911
Lymphocyte CD64 Index	0.22
Lymphocyte CD163 Index	265.26

Negative Control: Verify Lymphocyte CD64 Index is < 1.00 to Confirm Specificity of anti-CD64 Staining or Patient Exposure to Fluorescent Compounds.

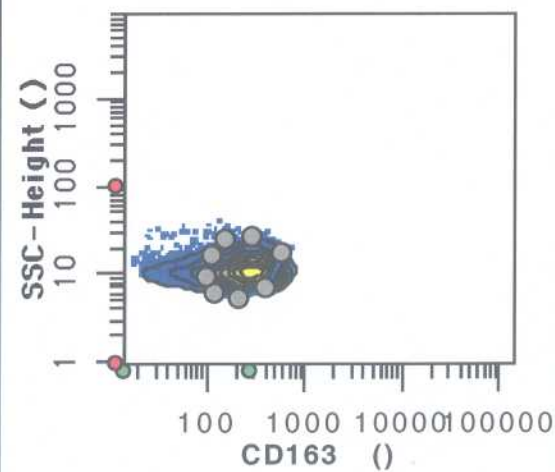
Gate1: Exclude Beads



Gate2: Crude Lymphs

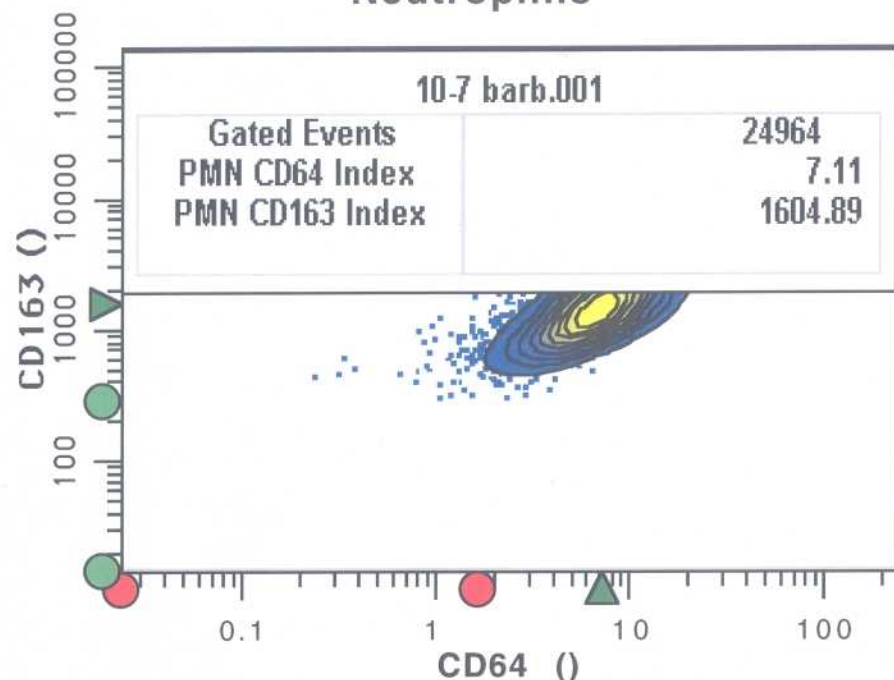


Gate3: Refined Lymphs



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Neutrophils

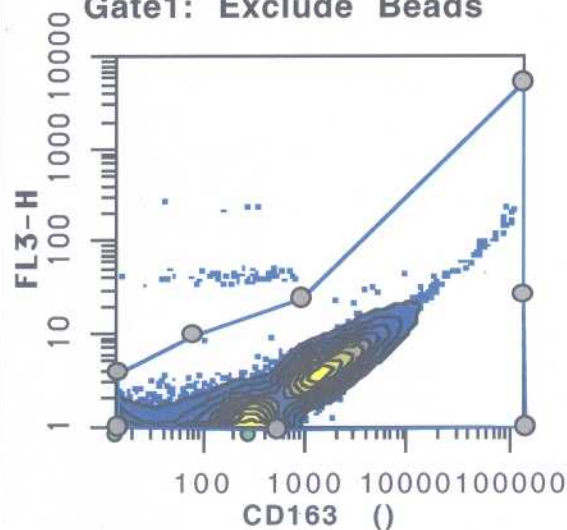


10-7 barb.001

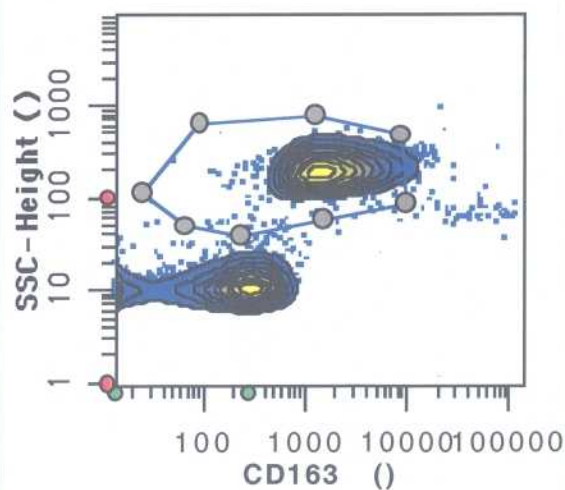
Gated Events	24964
PMN CD64 Index	7.11
PMN CD163 Index	1604.89

PMN CD64 Index values are typically < 1.00 in healthy individuals and a significant proportion of hospitalized patients without infection/sepsis will have PMN CD64 Index values in the 1.00 - 2.00 range, but every laboratory should establish their own normal or reference ranges. It is anticipated that clinical decision points may vary by age and among specific disease types.

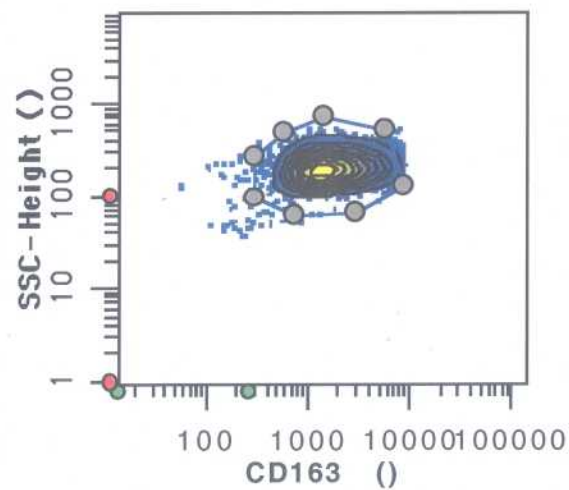
Gate1: Exclude Beads



Gate2: Crude PMNs

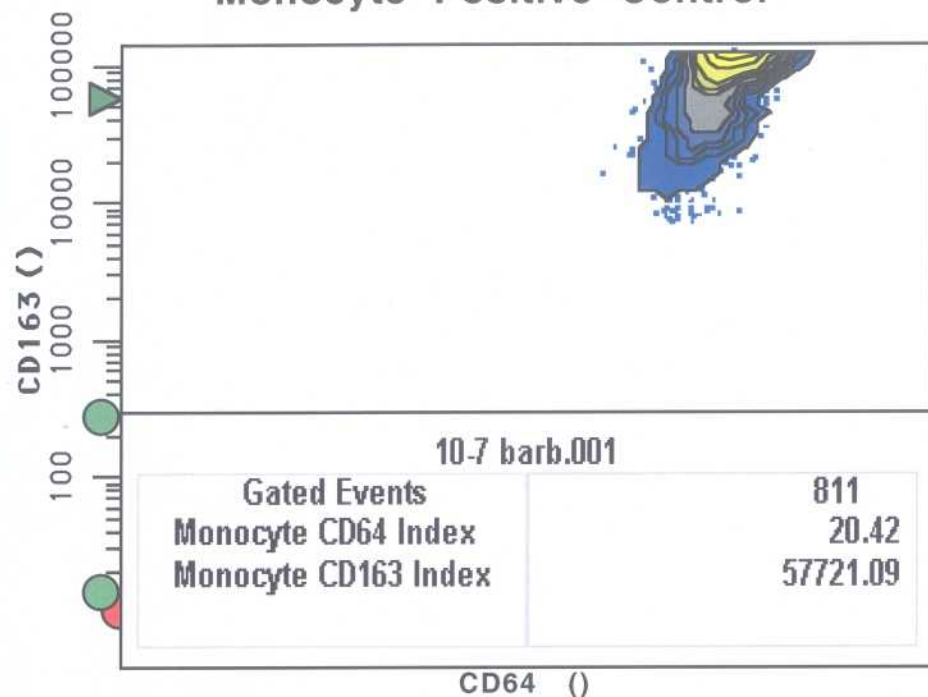


Gate3: Refined PMNs



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Monocyte Positive Control

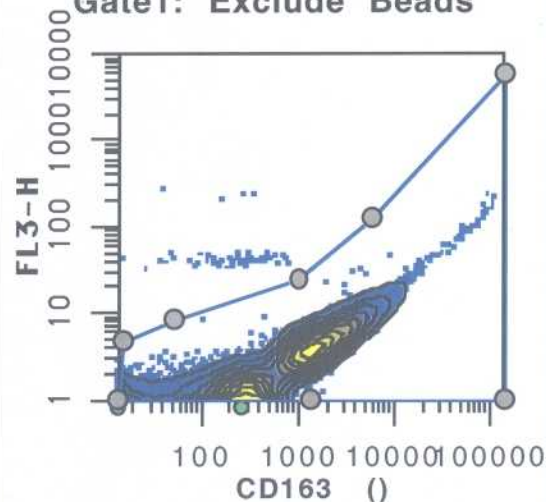


10-7 barb.001

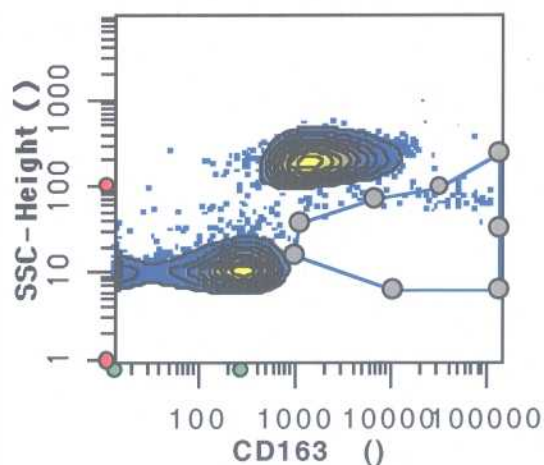
Gated Events	811
Monocyte CD64 Index	20.42
Monocyte CD163 Index	57721.09

Positive Control:
 Verify that Monocyte CD64 Index is >3.0 to demonstrate appropriate use of Reagent A.
 Monocytes are identified by the expression of CD163 (FL2 signal).

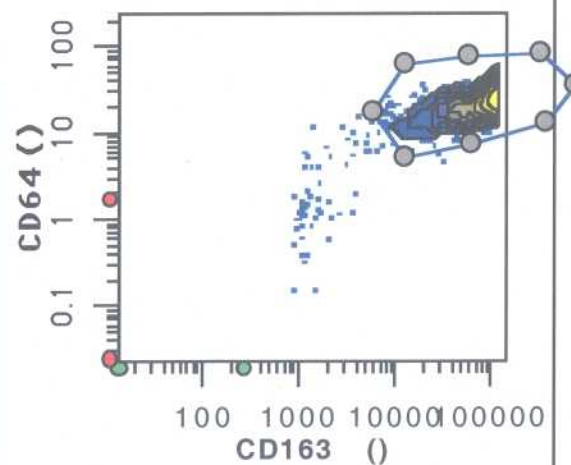
Gate1: Exclude Beads



Gate2: Crude Monocytes

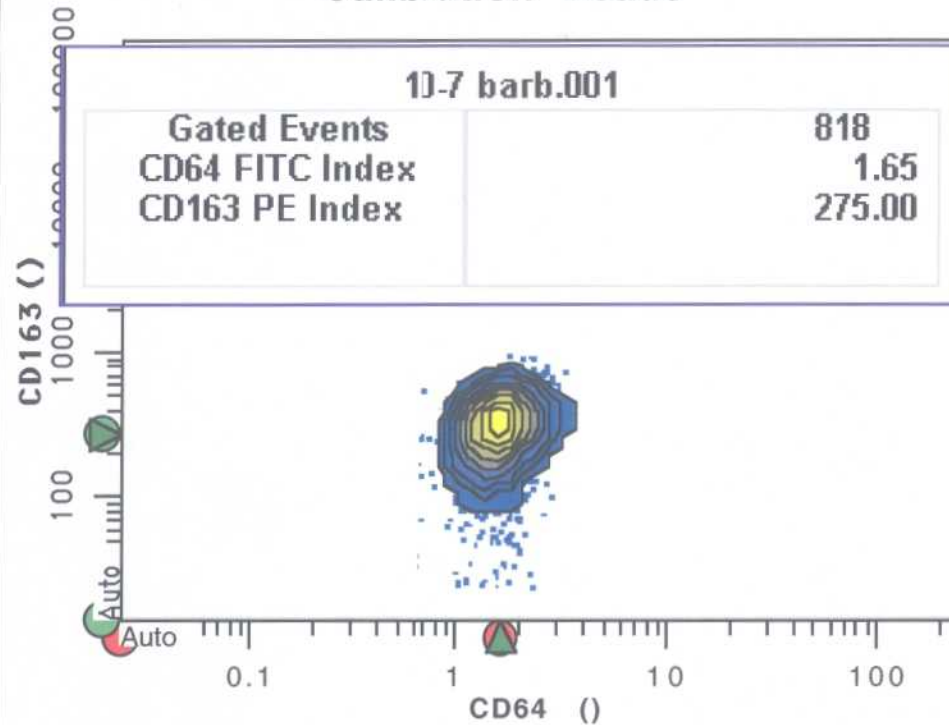


Gate3: Refined Monocytes



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Calibration Beads



10-7 barb.001

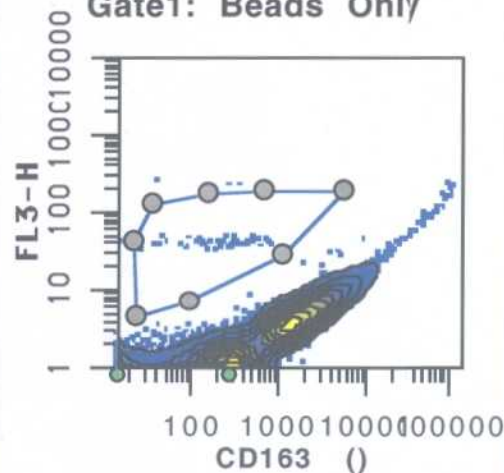
Gated Events	818
CD64 FITC Index	1.65
CD163 PE Index	275.00

Calibration Values for Lot Specific CD64 and CD163 Index Units with Data Collected on a BD Bioscience FACScan or FACScalibur Instrument.

Leuko64 Calibration Beads Lot #LK08-01
Expiration: 31 December 2010

It is important to follow instructions for use regarding instrument calibration and adjustments using the reagent C beads with each new lot of Leuko64. Mix samples thoroughly to avoid bead aggregates.

Gate1: Beads Only



Gate2: Bead Singlets

