



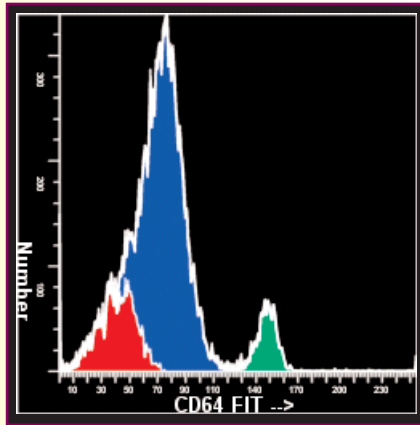
TRILLIUM DIAGNOSTICS, LLC

INNOVATIVE DIAGNOSTICS FOR CLINICAL CYTOMETRY AND LABORATORY HEMATOLOGY

Leuko64™

ASSAY FOR DETECTION OF INFLAMMATION AND TISSUE INJURY

C *For In Vitro Diagnostic Use*

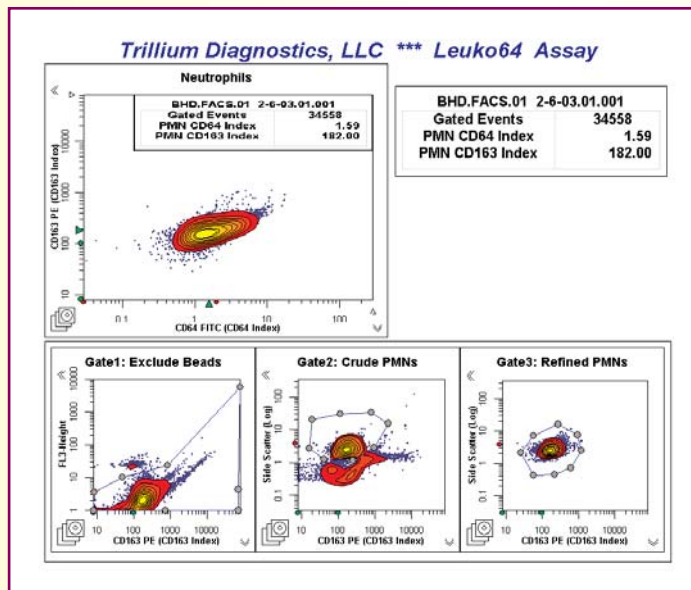


Neutrophil CD64 expression is rapidly increased both *in vitro* and *in vivo* within hours by mediators of inflammation, such as interferon-gamma and G-CSF. The same change is observed in response to documented infection or tissue injury, thus indicating that the measurement of neutrophil CD64 expression correlates with the presence of such conditions in humans.

The Leuko64 kit is composed of a mixture of three monoclonal antibodies with specificities to CD64 (both FITC conjugated) and CD163 (phycoerythrin conjugated), a concentrated lysing reagent, and a fluorescent bead suspension. The beads are used for instrument calibration and standardization of the leukocyte CD64 and CD163

expression in human blood. The Leuko64 assay is intended for use in the measurement of leukocyte neutrophil CD64 levels, which increase in response to tissue injury.

Automated software for flow cytometric listmode data analysis using iterative cluster finding algorithms is included in the assay kit. This software was co-developed with Verity Software House (www.vsh.com) and provides for objective data analysis and result reporting.



KEY FEATURES

- Requires only 50 µL of blood and under one hour of hands-on time.
- High correlation with presence of infection.
 - sensitivity 90.5%
 - specificity 96.3%
 - positive predictive value 95.0%
 - negative predictive value 92.9%
- Standardized assay with internal calibrator and controls.
- Automated user-friendly software allows for excellent reproducibility (CV <5%).



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PRODUCT LIST

FH-101	CE	IVD	FETALtrol™ Blood Controls	2 sets of 3 levels/kit
LK-064-75	CE	IVD	Leuko64™ Kit	75 tests
LK-064-250	CE	IVD	Leuko64™ Kit	250 tests
			CD64 Clone 22	
CD64-22F		ASR	▣ FITC (50 µg/mL)	1 mL
CD64-22P		ASR	▣ PE (25 µg/mL)	1 mL
CD64-22U		ASR	▣ Purified (100 µg/mL)	1 mL
			CD64 Clone 32.2	
CD64-322F		ASR	▣ FITC (50 µg/mL)	1 mL
CD64-322P		ASR	▣ PE (25 µg/mL)	1 mL
CD64-322U		ASR	▣ Purified (100 µg/mL)	1 mL
			CD163 Clone MAC-48	
CD163-48F		ASR	▣ FITC (50 µg/mL)	1 mL
CD163-48P		ASR	▣ PE (25 µg/mL)	1 mL
CD163-48U		ASR	▣ Purified (100 µg/mL)	1 mL
			CD163 Clone MAC-158	
CD163-158F		ASR	▣ FITC (50 µg/mL)	1 mL
CD163-158P		ASR	▣ PE (25 µg/mL)	1 mL
CD163-158U		ASR	▣ Purified (100 µg/mL)	1 mL
			CD163 Clone R20	
CD163-R20B		ASR	▣ biotinylated (100 µg/mL)	1 mL
CD163-R20U		ASR	▣ Purified (100 µg/mL)	1 mL

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