

# Routine diagnosis of inflammation and bacterial sepsis

**Leuko64™** by Trillium Diagnostics

Monitoring infection by the detection of CD64 on neutrophils  
on CELL-DYN 4000 and CELL-DYN Sapphire

**IVD** 



## Special features

- CD64 is an early-onset marker for inflammatory responses to infection or tissue injury
- Clear distinction between inflammation and conditions like leukemia, pregnancy or steroid therapy

## Clinical applications

- Screening for infection severity in outpatients and hospitalized patients including neonates
- Therapeutic monitor of antibiotic response in infection
- Monitoring post-operative and post-chemotherapy patients, HIV<sup>+</sup> patients, and others at risk for infection/sepsis

## Introduction

Inflammation is the complex biological response of vascular tissues to harmful stimuli, such as pathogens, damaged cells, or irritants. It is a protective attempt by the organism to remove the injurious stimuli as well as initiate the healing process for the tissue. Inflammation is not a synonym for infection. Infection is caused by an exogenous pathogen, while inflammation is the response of the organism to the pathogen.

An organism can escape the confines of the immediate tissue via the circulatory system or lymphatic system, where it may spread to other parts of the body. If an organism is not contained by the actions of acute inflammation it may gain access to the lymphatic system via nearby lymph vessels.

When inflammation overwhelms the host, systemic inflammatory response syndrome is diagnosed. When it is due to infection, the term sepsis is applied, with bacteremia being applied specifically for bacterial sepsis and viremia specifically to viral sepsis. Vasodilation and organ dysfunction are serious problems associated with widespread infection that may lead to septic shock and death.

Item	Description	Package size	Product code
Leuko64™-H	CELL-DYN™ 4000/ Sapphire version	100 tests	LK64-H-100

### Specifications

IVD CE

Requires only 50 µL of blood

Less than 15 minutes hands-on time

High correlation with presence of infection.

<i>Sensitivity</i>	90.5%
<i>Specificity</i>	96.3%
<i>Positive predictive value</i>	95.0%
<i>Negative predictive value</i>	92.9%
<i>Likelihood ratio</i>	24.46

Standardized assay with internal calibrator and controls.

Automated user-friendly software allows for excellent reproducibility (CV <5%)