



Certificate of Analysis

Product: GCAL
Lot No: GC0318
Exp. Date: 2018-06-30
Date of Manufacture: 2018-01-08

Parameter	Mean Light Scatter		% CV of the Population	
	Specification	Mean	Specification	Mean
ALL	125 ± 10	123	< 15 %	7.6
IAS	117 ± 10	121	< 17 %	10.6
PSS	115 ± 15	113	≤ 30 %	15.2
DSS	30.0 ± 5	31.8	≤ 30 %	22.1

Parameter	Specification		Mean
WBC 10 ⁹ /L	3.00 ± 0.50		3.10
NEUT%	> 90		97.3

Product Characteristics:

This material is a plasma-like fluid containing stabilized mammalian granulocytes. When stored at 2 to 8°C, unopened vials are stable until the expiration date. DO NOT FREEZE.

1. WARNING:

POTENTIALLY HAZARDOUS 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.

2. Lot uniformity studies verified product specifications were met and maintained in vial to vial testing.
3. Fill volumes were verified.
4. Microbiology testing meets specifications. These lots have been tested as per quality control procedures and found free of viable pathogenic or hemolytic microorganisms and fungi. This material is non-sterile.

This product has been manufactured according to all applicable FDA Good Manufacturing Practice regulations. These lots meet Manufacturing and Quality Assurance release specifications and are approved for release to Shipping/Marketing.

Approved by: Robert Wiśniewski
QMS Representative

Date: 31.01.2018