

Blood Controls

Certificate of Analysis Stabilised Human Whole Blood

RUO
REF

CFWB

LOT

29302



2015-05-09

 Start Date of Manufacture: **2015-02-12**

 Start Date of Quality Control Testing: **2015-02-16**

	Expected Values					
	% Positive	Range (%)		Absolute Count (cells/ μ l)	Range (cells/ μ l)	
		min	max		min	max
Lymphocytes	23.8	21.6	26.0	N/A	N/A	N/A
• CD3+	75.8	73.6	77.9	1064	912	1216
• CD3+ CD4+	58.4	56.1	60.6	820	712	928
• CD3+ CD8+	10.2	8.3	12.1	144	105	182
• NK Cells	8.8	7.0	10.6	124	95	152
• B Cells	15.0	12.5	17.6	211	157	265
Monocytes	3.9	3.4	4.4	N/A	N/A	N/A
Granulocytes	19.7	17.7	21.8	N/A	N/A	N/A

Pass Criterion:

The pass criterion is a less than 10% CV in the absolute count values for the cell subsets above across 10 separately stained tests performed at two different time points.

Comments:

10 separately stained tests were performed using Cytognos reagents and the lyse, no wash method across two consecutive days. All tests passed the acceptance criterion listed above and the averaged results and absolute counts can be found listed above.

Signature of Quality Control Manager

Date: 2015-02-23