

Blood Controls

Certificate of Analysis Stabilised Human Whole Blood

RUO
REF

CFWB

LOT

29380



2015-12-28

 Start Date of Manufacture: **2015-10-01**

 Start Date of Quality Control Testing: **2015-10-06**

	Expected Values					
	% Positive	Range (%)		Absolute Count (cells/ μ l)	Range (cells/ μ l)	
		min	max		min	max
Lymphocytes				N/A	N/A	N/A
• CD3+	77.2	75.3	79.1	1668	1511	1825
• CD3+ CD4+	43.8	41.0	46.6	953	817	1090
• CD3+ CD8+	31.4	29.3	33.5	680	599	761
• NK Cells	4.5	2.9	6.1	97	59	134
• B Cells	17.3	15.9	18.7	370	312	429

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 the BD Multitest IMK Kit with Trucount tubes 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: 2015-10-12