

Blood Controls

Certificate of Analysis CD4 Normal Blood Control

RUO
REF

CF04-N

LOT

29399



2016-03-07

 Start Date of Manufacture: **2015-12-09**

 Start Date of Quality Control Testing: **2015-12-15**

	Expected Values					
	% Positive	Range (%)		Absolute Count (cells/ μ l)	Range (cells/ μ l)	
		min	max		min	max
Lymphocytes	N/A	N/A	N/A	2825	2754	2901
• CD3+	80.6	79.1	82.1	2275	2135	2415
• CD3+ CD4+	67.8	64.1	71.5	1899	1669	2128
• CD3+ CD8+	10.8	9.5	12.1	306	260	352
• NK Cells	1.8	0.5	3.1	46	32	61
• B Cells	17.0	15.0	19.0	476	440	513

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: 2015-12-18