

Blood Controls

Certificate of Analysis CD4 Low Blood Control

RUO
REF

CF04-L

LOT

29400



2016-03-07

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

 Start Date of Quality Control Testing: **2015-12-17**

	Expected Values					
	% Positive	Range (%)		Absolute Count (cells/ μ l)	Range (cells/ μ l)	
		min	max		min	max
Lymphocytes	N/A	N/A	N/A	1837	1759	1954
• CD3+	56.7	54.7	58.7	1040	936	1144
• CD3+ CD4+	14.7	12.7	16.7	270	228	312
• CD3+ CD8+	37.6	35.5	39.7	691	600	782
• NK Cells	17.4	15.9	18.9	321	250	392
• B Cells	24.0	20.8	27.2	438	331	544

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
