

# Blood Controls

## Certificate of Analysis CD4 Normal Blood Control

**RUO**
**REF**

CF04-N

**LOT**

29378



2015-12-28

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

 Start Date of Quality Control Testing: **2015-10-05**

	Expected Values					
	% Positive	Range (%)		Absolute Count (cells/ $\mu$ l)	Range (cells/ $\mu$ l)	
		min	max		min	max
<b>Lymphocytes</b>				<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
• CD3+	82.6	80.5	84.7	1730	1622	1838
• CD3+ CD4+	52.5	50.9	54.1	1092	977	1207
• CD3+ CD8+	28.4	26.3	30.5	592	525	659
• NK Cells	2.0	2.0	2.0	41	29	53
• B Cells	14.8	12.9	16.7	315	277	353

**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**