

# Blood Controls

## Certificate of Analysis CD4 Low Blood Control

**RUO**
**REF**

CF04-L

**LOT**

29379



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/ $\mu$ 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+	58.0	56.6	59.4	1105	980	1230
• CD3+ CD4+	14.7	12.7	16.7	279	252	307
• CD3+ CD8+	40.5	38.4	42.6	772	641	902
• NK Cells	13.6	12.1	15.1	259	218	300
• B Cells	27.1	25.4	28.8	520	444	596

**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**