

TransFix[®]

RUO

LOT :



Description:

Reference:

Start Date of Manufacture:

Start Date of Quality Control Testing:

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	72.4	71.8	0.8	Pass
% CD4+	79.4	79.2	0.2	Pass
CD3+ Abs Cnt	1382	1309	5.3	Pass
CD4+ Abs Cnt	1097	1036	5.6	Pass
CD8+ Abs Cnt	268	256	4.2	Pass
CD45+ Abs Cnt	1949	1835	5.9	Pass

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The pass criterion is a less than 15% difference between the lymphocyte absolute count (CD45+ Abs Cnt), T cell absolute count and % (CD3+), T helper cell absolute count and % (CD4+) and cytotoxic T cell absolute count (CD8+) on day 0 and day 11.

3 separately stained tests were performed at each of the time points. These results were averaged and all parameters passed the acceptance criterion.

Signature of Quality Control Manager



Date: 2025-07-10