

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent


LOT : 29388


: 2017-10-20

Start Date of Manufacture: **2015-10-20**

Start Date of Quality Control Testing: **2015-10-23**

	A	B		
	TransFix Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	70.8	73.5	3.8	PASS
% CD4+	43.8	44.2	1.0	PASS
CD3+ Abs Cnt	1314	1281	2.5	PASS
CD4+ Abs Cnt	812	771	5.1	PASS
CD8+ Abs Cnt	332	324	2.3	PASS
CD45+ Abs Cnt	1855	1743	6.1	PASS

Pass Criterion:

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.

Comments:

5 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: 2015-11-11

