

TransFix®

Certificate of Analysis TransFix® Cellular Antigen Stabilisation Reagent



 : 29389

 : 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+	71.8	74.1	3.2	PASS
% CD4+	44.1	44.9	2.0	PASS
CD3+ Abs Cnt	1318	1414	7.3	PASS
CD4+ Abs Cnt	809	858	6.1	PASS
CD8+ Abs Cnt	333	355	6.7	PASS
CD45+ Abs Cnt	1837	1909	3.9	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

