

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29507

 : 2018-09-08

Start Date of Manufacture: 2016-09-08

Start Date of Quality Control Testing: 2016-09-16

	A	B		
	TransFix Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	77.7	75.7	2.6	PASS
% CD4+	53.8	50.8	5.6	PASS
CD3+ Abs Cnt	1249	1262	1.1	PASS
CD4+ Abs Cnt	970	956	1.4	PASS
CD8+ Abs Cnt	522	486	6.9	PASS
CD45+ Abs Cnt	297	301	1.4	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:

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: 2016-10-07

