

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29532

 : 2018-10-20

Start Date of Manufacture: **2016-10-20**

Start Date of Quality Control Testing: **2017-01-27**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	81.8	81.1	0.9	PASS
% CD4+	34.3	34.5	0.6	PASS
CD3+ Abs Cnt	1533	1393	8.3	PASS
CD4+ Abs Cnt	526	480	9.1	PASS
CD8+ Abs Cnt	824	752	8.7	PASS
CD45+ Abs Cnt	1874	1719	8.6	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: 2017-03-02

