

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29622

 : 2019-09-29

Start Date of Manufacture: **2017-09-29**

Start Date of Quality Control Testing: **2017-10-12**

	A	B		
	TransFix Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	73.7	72.3	1.8	PASS
% CD4+	42.0	41.3	1.6	PASS
CD3+ Abs Cnt	1444	1385	4.1	PASS
CD4+ Abs Cnt	833	808	3.0	PASS
CD8+ Abs Cnt	572	537	6.1	PASS
CD45+ Abs Cnt	1971	1919	2.6	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: 2017-10-23

