

# TransFix<sup>®</sup>

## Certificate of Analysis TransFix<sup>®</sup> Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29454

 : 2018-04-08

Start Date of Manufacture: 2016-04-08

Start Date of Quality Control Testing: 2016-04-22

	A	B		
	TransFix Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.8	77.5	0.9	PASS
% CD4+	47.5	46.7	1.6	PASS
CD3+ Abs Cnt	1075	1004	6.6	PASS
CD4+ Abs Cnt	510	469	8.1	PASS
CD8+ Abs Cnt	326	311	4.8	PASS
CD45+ Abs Cnt	1399	1296	7.4	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: 2016-05-06

