

# TransFix<sup>®</sup>

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

CE

IVD

LOT : 29546

 : 2019-02-16

Start Date of Manufacture: **2017-02-16**

Start Date of Quality Control Testing: **2017-02-24**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.3	77.4	1.4	PASS
% CD4+	63.5	68.0	7.1	PASS
CD3+ Abs Cnt	1276	1592	4.8	PASS
CD4+ Abs Cnt	809	1232	3.4	PASS
CD8+ Abs Cnt	303	838	3.5	PASS
CD45+ Abs Cnt	1673	300	0.9	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:

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: 2017-03-07