

# TransFix<sup>®</sup>

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

**CE**
**IVD**
**LOT** : 29508

 : 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	77.0	0.9	PASS
% CD4+	53.8	52.2	3.0	PASS
CD3+ Abs Cnt	1249	1288	3.2	PASS
CD4+ Abs Cnt	970	992	2.2	PASS
CD8+ Abs Cnt	522	518	0.8	PASS
CD45+ Abs Cnt	297	297	0.1	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

