

# TransFix®

## Certificate of Analysis TransFix® Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29844

 : 2021-07-15

Start Date of Manufacture: **2019-07-15**

Start Date of Quality Control Testing: **2019-07-18**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	75.9	75.4	0.7	PASS
% CD4+	47.7	45.6	4.4	PASS
CD3+ Abs Cnt	989	892	9.8	PASS
CD4+ Abs Cnt	472	406	13.8	PASS
CD8+ Abs Cnt	345	308	10.5	PASS
CD45+ Abs Cnt	1303	1183	9.2	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: 08 Nov 2019

