

# TransFix<sup>®</sup>

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

CE

IVD

LOT : 29915

 : 2022-09-28

Start Date of Manufacture: **2020-09-28**

Start Date of Quality Control Testing: **2020-10-08**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	79.1	81.1	2.5	PASS
% CD4+	60.2	60.2	0.1	PASS
CD3+ Abs Cnt	1471	1416	3.7	PASS
CD4+ Abs Cnt	885	853	3.6	PASS
CD8+ Abs Cnt	569	548	3.6	PASS
CD45+ Abs Cnt	3807	3544	6.9	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: 19 Oct 2020