

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29890

 : 2022-01-28

Start Date of Manufacture: **2020-01-28**

Start Date of Quality Control Testing: **2020-02-18**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	72.0	71.3	0.9	PASS
% CD4+	74.0	72.5	2.0	PASS
CD3+ Abs Cnt	1395	1541	10.5	PASS
CD4+ Abs Cnt	1032	1117	8.2	PASS
CD8+ Abs Cnt	265	294	11.1	PASS
CD45+ Abs Cnt	1938	2159	11.4	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: 03 Mar 2020