

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29756

 : 2020-10-15

Start Date of Manufacture: **2018-10-15**

Start Date of Quality Control Testing: **2018-11-08**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	79.8	81.6	2.3	Pass
% CD4+	36.9	37.5	1.6	Pass
CD3+ Abs Cnt	1040	1136	9.3	Pass
CD4+ Abs Cnt	384	426	10.9	Pass
CD8+ Abs Cnt	516	566	9.8	Pass
CD45+ Abs Cnt	1304	1393	6.8	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: 27 NOV 2018