

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent



LOT : 29722

 : 2020-05-22

Start Date of Manufacture: **2018-05-22**

Start Date of Quality Control Testing: **2018-05-31**

	A	B		
	Control Day 0	TransFix Day 13	% Diff (A-B)/A	Pass / Fail
% CD3+	70.6	72.1	2.0	PASS
% CD4+	65.1	63.8	2.0	PASS
CD3+ Abs Cnt	1428	1344	5.9	PASS
CD4+ Abs Cnt	930	857	7.8	PASS
CD8+ Abs Cnt	313	278	11.4	PASS
CD45+ Abs Cnt	2022	1865	7.8	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 13.

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: 2018-06-25

