

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent



LOT : 29680

 : 2020-03-05

 Start Date of Manufacture: **2018-03-05**

 Start Date of Quality Control Testing: **2018-03-08**

	A	B		
	TransFix Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	69.9	70.4	0.7	PASS
% CD4+	65.0	64.1	1.5	PASS
CD3+ Abs Cnt	1393	1338	3.9	PASS
CD4+ Abs Cnt	906	857	5.4	PASS
CD8+ Abs Cnt	308	294	4.4	PASS
CD45+ Abs Cnt	1992	1900	4.6	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: 2018-03-20

