

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent



LOT : 29474

 : 2018-06-02

Start Date of Manufacture: **2016-06-02**

Start Date of Quality Control Testing: **2016-07-08**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	77.3	76.0	1.7	PASS
% CD4+	42.2	41.4	2.0	PASS
CD3+ Abs Cnt	1954	1763	9.8	PASS
CD4+ Abs Cnt	1511	1339	11.4	PASS
CD8+ Abs Cnt	638	554	13.3	PASS
CD45+ Abs Cnt	733	645	12.0	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: 2016-07-21

