

TransFix[®]

Certificate of Analysis TransFix[®]/EDTA CSF Sample Storage Tubes

RUO

LOT : 29481

 : 2017-07-08

Start Date of Manufacture: **2016-07-08**

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

	A	B		
	Control Day 0	TransFix/EDTA Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	77.3	76.7	0.8	PASS
% CD4+	42.2	41.4	1.8	PASS
CD3+ Abs Cnt	1954	1778	9.0	PASS
CD4+ Abs Cnt	1511	1364	9.7	PASS
CD8+ Abs Cnt	638	566	11.4	PASS
CD45+ Abs Cnt	733	671	8.5	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

