

TransFix[®]

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

RUO
LOT : 29517

 : 2017-10-19

 Start Date of Manufacture: **2016-10-19**

 Start Date of Quality Control Testing: **2016-11-11**

	A	B		
	Control Day 0	TransFix/EDTA Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	82.5	77.5	6.2	PASS
% CD4+	32.8	32.8	0.1	PASS
CD3+ Abs Cnt	1378	1326	3.8	PASS
CD4+ Abs Cnt	452	435	3.7	PASS
CD8+ Abs Cnt	780	740	5.1	PASS
CD45+ Abs Cnt	1670	1713	2.6	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: 2016-12-08

