

TransFix[®]

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

RUO

LOT : 29395

 : 2016-11-12

Start Date of Manufacture: **2015-11-12**

Start Date of Quality Control Testing: **2015-11-12**

	A	B		
	TransFix/EDTA Day 0	TransFix/EDTA Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.5	75.2	1.7	PASS
% CD4+	34.5	31.9	7.6	PASS
CD3+ Abs Cnt	1319	1242	5.9	PASS
CD4+ Abs Cnt	594	526	11.4	PASS
CD8+ Abs Cnt	445	391	12.1	PASS
CD45+ Abs Cnt	1724	1650	4.3	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 10.

Comments:

5 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: 2015-11-24