

TransFix[®]

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

RUO
LOT : 29457

 : 2017-04-18

 Start Date of Manufacture: **2016-04-18**

 Start Date of Quality Control Testing: **2016-05-05**

	A	B		
	TransFix/EDTA Day 0	TransFix/EDTA Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	74.5	73.6	1.3	PASS
% CD4+	50.1	50.3	0.4	PASS
CD3+ Abs Cnt	1417	1268	10.5	PASS
CD4+ Abs Cnt	1057	933	11.7	PASS
CD8+ Abs Cnt	529	469	11.4	PASS
CD45+ Abs Cnt	329	296	9.8	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: 2016-05-17

