

TransFix[®]

Certificate of Analysis TransFix[®]/EDTA Vacuum Blood Collection Tubes (TVT)



LOT : 29463

 : 2017-11

 Start Date of Manufacture: **2016-05-16**

 TransFix Batch Number used in TVT manufacture: **29454**

 Start Date of Quality Control Testing: **2016-06-02**

	A	B		
	TVT Day 0	TVT Day 12	% Diff (A-B)/A	Pass / Fail
% CD3+	76.0	76.5	0.6	PASS
% CD4+	48.4	47.3	2.3	PASS
CD3+ Abs Cnt	1494	1373	8.1	PASS
CD4+ Abs Cnt	951	849	10.7	PASS
CD8+ Abs Cnt	420	402	4.2	PASS
CD45+ Abs Cnt	1966	1796	8.6	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 12.

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: 2016-06-15

