

TransFix[®]

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



LOT : 29603

 : 2019-03-31

 Start Date of Manufacture: **2017-08-02**

 TransFix Batch Number used in TVT manufacture: **29546**

 Start Date of Quality Control Testing: **2017-09-14**

	A	B		
	TVT Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	74.4	79.6	7.0	PASS
% CD4+	64.1	61.4	4.2	PASS
CD3+ Abs Cnt	1362	1462	7.3	PASS
CD4+ Abs Cnt	873	897	2.8	PASS
CD8+ Abs Cnt	382	393	2.8	PASS
CD45+ Abs Cnt	1832	1838	0.3	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 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: 2017-09-25

