

TransFix[®]

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



LOT : 29689



: 2019-09-30

Start Date of Manufacture: **2018-03-16**

TransFix Batch Number used in TVT manufacture: **29598**

Start Date of Quality Control Testing: **2018-05-04**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	83.6	83.5	0.1	PASS
% CD4+	35.4	36.0	1.6	PASS
CD3+ Abs Cnt	1416	1286	9.2	PASS
CD4+ Abs Cnt	501	463	7.7	PASS
CD8+ Abs Cnt	728	672	7.7	PASS
CD45+ Abs Cnt	1694	1541	9.1	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: 2018-05-16

