

TransFix[®]

Certificate of Analysis

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

IVD
REF : TVT-03-50-US

LOT : 29594

 : 2019-01-31

 Start Date of Manufacture: **2017-07-04**

 TransFix Batch Number used in TVT manufacture: **29545**

 Start Date of Quality Control Testing: **2017-07-24**

	A	B		
	Control Day 0	TVT Day 15	% Diff (A-B)/A	Pass / Fail
% CD3+	66.4	62.4	6.0	PASS
% CD4+	39.6	36.1	8.7	PASS
CD3+ Abs Cnt	1327	1293	2.6	PASS
CD4+ Abs Cnt	775	750	3.1	PASS
CD8+ Abs Cnt	433	433	0.1	PASS
CD45+ Abs Cnt	1998	2077	4.0	PASS

Pass Criterion:

The pass criterion is a less than 15% difference between the blood 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 15.

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: 2017-08-08

