

TransFix[®]

Certificate of Analysis

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



 : TVT-09-1, TVT-09-2, TVT-09-50
  : 29746

 : 2020-03-31

Start Date of Manufacture: **2018-08-21**

TransFix Batch Number used in TVT manufacture: **29721**

Start Date of Quality Control Testing: **2018-09-20**

	A	B		
	Control Day 0	TVT Day 12	% Diff (A-B)/A	Pass / Fail
% CD3+	81.1	80.3	1.0	PASS
% CD4+	36.5	37.7	3.2	PASS
CD3+ Abs Cnt	1177	1176	0.1	PASS
CD4+ Abs Cnt	430	443	3.1	PASS
CD8+ Abs Cnt	600	583	2.8	PASS
CD45+ Abs Cnt	1451	1464	0.9	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 12.

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: 04 OCT 2018

