




TransFix[®]

Certificate of Analysis

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



 : TVT-03-1, TVT-03-2, TVT-03-50
  : 29873

 : 2021-05-31

Start Date of Manufacture: **2019-11-13**

TransFix Batch Number used in TVT manufacture: **29820**

Start Date of Quality Control Testing: **2019-12-05**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	77.7	78.3	0.9	PASS
% CD4+	31.7	32.7	3.2	PASS
CD3+ Abs Cnt	1613	1539	4.6	PASS
CD4+ Abs Cnt	676	645	4.6	PASS
CD8+ Abs Cnt	927	849	8.4	PASS
CD45+ Abs Cnt	2079	1962	5.6	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 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

Nkaanzig

Date: 17 Dec 2019

