

TransFix[®]

Certificate of Analysis

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

RUO **REF** : TVT-09-1-RUO, TVT-09-2-RUO, TVT-09-50-RUO **LOT** : 29802

 : 2020-09-30

Start Date of Manufacture: **2019-02-25**

TransFix Batch Number used in TVT manufacture: **29797**

Start Date of Quality Control Testing: **2019-04-17**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	72.7	69.3	4.6	PASS
% CD4+	43.0	40.7	5.4	PASS
CD3+ Abs Cnt	1515	1572	3.8	PASS
CD4+ Abs Cnt	884	915	3.6	PASS
CD8+ Abs Cnt	604	607	0.5	PASS
CD45+ Abs Cnt	2076	2306	11.0	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:

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: 18 JULY 2019

