

TransFix[®]

Certificate of Analysis

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

RUO **REF** : TVT-03-1-RUO, TVT-03-2-RUO, TVT-03-50-RUO **LOT** : 29957

 : 2023-07-31

Start Date of Manufacture: **2022-01-20**

TransFix Batch Number used in TVT manufacture: **29946**

Start Date of Quality Control Testing: **2020-03-03**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	73.7	73.3	0.5	PASS
% CD4+	54.9	55.0	0.0	PASS
CD3+ Abs Cnt	1497	1643	9.7	PASS
CD4+ Abs Cnt	823	903	9.8	PASS
CD8+ Abs Cnt	629	664	5.6	PASS
CD45+ Abs Cnt	2081	2309	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 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: 23 Aug 2022

