

TransFix[®]

Certificate of Analysis

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



 : TVT-03-1, TVT-03-2, TVT-03-50
  : 29810

 : 2020-10-31

Start Date of Manufacture: **2019-03-11**

TransFix Batch Number used in TVT manufacture: **29784**

Start Date of Quality Control Testing: **2019-05-30**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	70.1	70.0	0.1	PASS
% CD4+	61.6	62.0	0.6	PASS
CD3+ Abs Cnt	1148	1154	0.5	PASS
CD4+ Abs Cnt	707	715	1.1	PASS
CD8+ Abs Cnt	319	330	3.2	PASS
CD45+ Abs Cnt	1638	1648	0.6	PASS

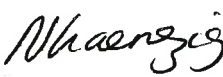
Pass Criterion:

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


 Date: 14 JUN 2019

