

TransFix[®]

Certificate of Analysis

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



 : TVT-03-1, TVT-03-2, TVT-03-50
  : 29869

 : 2021-04-30

Start Date of Manufacture: **2019-10-24**

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

Start Date of Quality Control Testing: **2019-11-14**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	78.3	74.3	5.1	PASS
% CD4+	30.7	29.3	4.3	PASS
CD3+ Abs Cnt	1437	1500	4.4	PASS
CD4+ Abs Cnt	556	585	5.1	PASS
CD8+ Abs Cnt	821	867	5.7	PASS
CD45+ Abs Cnt	1835	2025	10.4	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: 27 Nov 2019

