

TransFix[®]

Certificate of Analysis

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

IVD
REF : TVT-03-2-US, TVT-03-50-US
LOT : 29870
 : 2021-04-30

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

TransFix Batch Number used in TVT manufacture: **29843**

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

	A	B		
	Control Day 0	TVT Day 15	% Diff (A-B)/A	Pass / Fail
% CD3+	78.3	77.0	1.7	PASS
% CD4+	30.7	29.7	3.3	PASS
CD3+ Abs Cnt	1437	1456	1.3	PASS
CD4+ Abs Cnt	556	561	0.8	PASS
CD8+ Abs Cnt	821	802	2.3	PASS
CD45+ Abs Cnt	1835	1895	3.3	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: 27 Nov 2019

