

TransFix[®]

Certificate of Analysis

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

**REF**

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

LOT

: 30025



: 2024-12-31

Start Date of Manufacture: **2023-06-27**TransFix Batch Number used in TVT manufacture: **30021**Start Date of Quality Control Testing: **2023-07-06**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	84.3	82.0	2.7	PASS
% CD4+	38.2	36.4	4.8	PASS
CD3+ Abs Cnt	1269	1240	2.3	PASS
CD4+ Abs Cnt	485	451	7.0	PASS
CD8+ Abs Cnt	675	643	4.8	PASS
CD45+ Abs Cnt	1541	1536	0.3	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 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: 20 July 2023