

TransFix[®]

Certificate of Analysis

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

CE IVD

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

LOT : 30037



: 2025-06-30

Start Date of Manufacture: **2023-11-30**

TransFix Batch Number used in TVT manufacture: **30028**

Start Date of Quality Control Testing: **2024-03-07**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	74.9	73.6	1.7	PASS
% CD4+	79.2	77.0	2.8	PASS
CD3+ Abs Cnt	1476	1344	8.9	PASS
CD4+ Abs Cnt	1169	1033	11.7	PASS
CD8+ Abs Cnt	280	247	11.6	PASS
CD45+ Abs Cnt	2019	1868	7.5	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: 21 Mar 2024