

TransFix[®]

Certificate of Analysis

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

CE IVD

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

LOT : 30053



: 2025-12-31

Start Date of Manufacture: **2024-05-30**

TransFix Batch Number used in TVT manufacture: **30047**

Start Date of Quality Control Testing: **2024-06-20**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	83.4	83.3	0.1	PASS
% CD4+	49.8	49.1	1.4	PASS
CD3+ Abs Cnt	2183	2158	1.1	PASS
CD4+ Abs Cnt	1087	1059	2.6	PASS
CD8+ Abs Cnt	868	925	6.6	PASS
CD45+ Abs Cnt	2662	2662	0.0	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: 04 Jul 2024