

TransFix[®]

Certificate of Analysis

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

RUO **REF** : TVT-03-1-RUO, TVT-03-2-RUO, TVT-03-50-RUO **LOT** : 30029

 : 2025-02-28

Start Date of Manufacture: **2023-08-29**

TransFix Batch Number used in TVT manufacture: **30021**

Start Date of Quality Control Testing: **2023-09-14**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	78.5	76.9	2.0	PASS
% CD4+	56.9	55.9	1.7	PASS
CD3+ Abs Cnt	3578	3367	5.9	PASS
CD4+ Abs Cnt	2034	1882	7.5	PASS
CD8+ Abs Cnt	1393	1289	7.5	PASS
CD45+ Abs Cnt	4667	4544	2.6	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: 01 May 2024