

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** : 30062

 : 2026-03-31

Start Date of Manufacture: **2024-09-12**

TransFix Batch Number used in TVT manufacture: **30060**

Start Date of Quality Control Testing: **2024-10-03**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	74.9	72.9	2.6	Pass
% CD4+	78.1	80.1	2.6	Pass
CD3+ Abs Cnt	1263	1184	6.2	Pass
CD4+ Abs Cnt	986	948	3.8	Pass
CD8+ Abs Cnt	233	223	4.2	Pass
CD45+ Abs Cnt	1722	1678	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: 16 Oct 2024