

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** : 30068

 : 2026-08-31

Start Date of Manufacture: **2025-02-03**

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

Start Date of Quality Control Testing: **2025-02-20**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.3	74.9	1.8	PASS
% CD4+	82.6	81.1	1.9	PASS
CD3+ Abs Cnt	1176	1119	4.9	PASS
CD4+ Abs Cnt	972	907	6.7	PASS
CD8+ Abs Cnt	200	193	3.6	PASS
CD45+ Abs Cnt	1587	1533	3.4	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

N Woodham

Date: 04 Mar 2025