

# TransFix<sup>®</sup>

## Certificate of Analysis TransFix<sup>®</sup>/EDTA CSF Sample Storage Tubes

**RUO**
**LOT** : 29654

 : 2018-12-31

 Start Date of Manufacture: **2017-12-18**

 Start Date of Quality Control Testing: **2017-12-21**

	A	B		
	TransFix/EDTA Day 0	TransFix/EDTA Day 12	% Diff (A-B)/A	Pass / Fail
% CD3+	78.9	79.5	0.8	PASS
% CD4+	36.2	36.4	0.5	PASS
CD3+ Abs Cnt	1342	1180	12.1	PASS
CD4+ Abs Cnt	486	429	11.6	PASS
CD8+ Abs Cnt	682	611	10.5	PASS
CD45+ Abs Cnt	1701	1484	12.8	PASS

**Pass Criterion:**

The pass criterion is a less than 15% difference between the 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 12.

**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: 2018-01-26