

# TransFix<sup>®</sup>

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

**RUO**

**REF**: TF-CSF-5-2, TF-CSF-5-10, **LOT**: 29727

TF-CSF-5-25, and TF-CSF-5-50



: 2019-06-30

Start Date of Manufacture: **2018-06-11**

Start Date of Quality Control Testing: **2018-06-21**

	A	B		
	Control Day 0	TransFix/EDTA Day 4	% Diff (A-B)/A	Pass / Fail
% Monocytes	20.8	20.5	1.2	PASS
% CD4+ T cells	59.7	60.4	1.1	PASS
% CD8+ T cells	29.4	28.5	3.2	PASS
% B cells	12.7	10.9	13.7	PASS
% Igκ+ B cells	62.2	58.2	6.3	PASS
% Igλ+ B cells	37.8	41.8	10.4	PASS
% NK cells	14.6	12.8	12.3	PASS

### Pass Criterion:

The pass criterion is a less than 15% difference between monocyte partial % (CD14+), T helper cell partial % (CD4+), cytotoxic T cell partial % (CD8+), B cell partial % (CD19+, CD20+), Ig Kappa+ B cell partial % (Igκ+), Ig Lambda+ B cell partial % (Igλ+) and NK cell partial % (CD56+) on day 0 and day 4.

### 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 CSO



Date: 2018-06-25



**Histograms:**

Shaded histograms represent fluorescence intensity results for TransFix/EDTA stabilized human leukocytes within a CSF substitute stained with the SST screening kit (Cytgnos) after 4 days of storage at 2-8°C.

Transparent histograms represent the equivalent un-stabilized CSF preparation of leukocytes in CSF substitute (Control – Day 0) for the positive subpopulation.

Analysis was conducted using Infinicyt software (Cytgnos).

