

TransFix[®]

Certificate of Analysis TransFix[®]/EDTA CSF Sample Storage Tubes

RUO

REF: TF-CSF-5-2, TF-CSF-5-10, **LOT**: 29677

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



: 2019-03-31

Start Date of Manufacture: 2018-03-01

Start Date of Quality Control Testing: 2018-03-01

	A	B		
	Control Day 0	TransFix/EDTA Day 4	% Diff (A-B)/A	Pass / Fail
% Monocytes	8.9	7.8	11.7	PASS
% CD4+ T cells	54.3	51.8	4.6	PASS
% CD8+ T cells	37.1	36.5	1.6	PASS
% B cells	5.3	4.7	11.9	PASS
% Igκ+ B cells	62.8	60.0	4.5	PASS
% Igλ+ B cells	37.2	40.0	7.6	PASS
% NK cells	15.4	15.5	0.3	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 Chief Scientific Officer



Date: 2018-03-05



Histograms:

Shaded histograms represent fluorescence intensity results for TransFix/EDTA stabilized human leukocytes within a CSF substitute stained with the SST screening kit (Cytognos) 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 (Cytognos).

