

TransFix[®]

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

RUO

REF: TF-CSF-5-2, TF-CSF-5-10, **LOT**: 29744

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



: 2019-08-31

Start Date of Manufacture: 2018-08-03

Start Date of Quality Control Testing: 2018-08-03

	A	B		
	Control Day 0	TransFix/EDTA Day 4	% Diff (A-B)/A	Pass / Fail
% Monocytes	18.3	18.7	2.3	PASS
% CD4+ T cells	65.0	57.0	12.4	PASS
% CD8+ T cells	24.5	24.2	1.4	PASS
% B cells	10.1	8.7	14.5	PASS
% Igκ+ B cells	62.0	58.2	6.2	PASS
% Igλ+ B cells	38.0	41.8	10.0	PASS
% NK cells	12.8	12.3	4.3	PASS

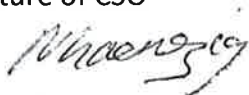
Pass Criterion:

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: 2018-08-07



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).

