

TransFix®

Certificate of Analysis TransFix®/EDTA CSF Sample Storage Tubes

RUO

REF: TF-CSF-5-2, TF-CSF-5-10, **LOT**: 29826
TF-CSF-5-25, and TF-CSF-5-50

 : 2020-05-31

Start Date of Manufacture: 2019-05-30

Start Date of Quality Control Testing: 2019-06-06

	A	B		
	Control Day 0	TransFix/EDTA Day 4	% Diff (A-B)/A	Pass / Fail
% Monocytes	9.3	8.7	6.4	PASS
% CD4+ T cells	51.4	55.9	8.8	PASS
% CD8+ T cells	38.6	37.2	3.7	PASS
% B cells	5.1	5.4	5.6	PASS
% Igκ+ B cells	58.2	54.1	6.9	PASS
% Igλ+ B cells	41.8	45.9	9.6	PASS
% NK cells	18.0	16.7	7.3	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 Quality Control Manager

M. Wenzel

Date: 10 JUL 2019

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).

