



Certificate of Analysis TransFix® Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 3006

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2027-01-31

Description: TransFix Bulk

Reference: TFB-01-1, TFB-01-10, TFB-01-50 and TFB-20-1

Start Date of Manufacture: 2025-01-16

Start Date of Quality Control Testing: 2025-02-20

	Α	В		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.3	75.8	0.7	Pass
% CD4+	82.6	81.4	1.4	Pass
CD3+ Abs Cnt	1176	1070	9.1	Pass
CD4+ Abs Cnt	972	871	10.4	Pass
CD8+ Abs Cnt	200	181	9.4	Pass
CD45+ Abs Cnt	1587	1451	8.6	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 11.

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: 04 Mar 2025

NWoodham