

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent

CE**IVD****LOT** : 30034 : 2025-11-30Start Date of Manufacture: **2023-11-02**Start Date of Quality Control Testing: **2023-11-23**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	75.4	73.3	2.8	PASS
% CD4+	56.5	57.4	1.5	PASS
CD3+ Abs Cnt	1450	1302	10.2	PASS
CD4+ Abs Cnt	820	748	8.9	PASS
CD8+ Abs Cnt	567	498	12.2	PASS
CD45+ Abs Cnt	1954	1776	9.1	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: 14 Dec 2023