

TransFix®

Certificate of Analysis TransFix® Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29843

⏳ : 2021-07-15

Start Date of Manufacture: **2019-07-15**

Start Date of Quality Control Testing: **2019-07-18**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	75.9	74.6	1.7	PASS
% CD4+	47.7	46.2	3.2	PASS
CD3+ Abs Cnt	989	960	2.9	PASS
CD4+ Abs Cnt	472	443	6.0	PASS
CD8+ Abs Cnt	345	331	3.9	PASS
CD45+ Abs Cnt	1303	1287	1.2	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

Nhaengiz

Date: 22 AUG 2019