

TransFix[®]

Certificate of Analysis Circulating Tumor Cell TransFix[®]/EDTA Vacuum Blood Collection Tubes (CTC-TVT)

REF : CTC-TVT-09-2, CTC-TVT-09-50

LOT : 29666

 : 2019-02-28

Start Date of Manufacture: 2018-02-05

Start Date of Quality Control Testing: 2018-03-22

CD45-/EPCAM+ SKBR3 Cells at 10000 cells/mL			
Control Day 0	Control Day 6	CTC-TVT Day 0	CTC-TVT Day 6
Events Present	Events Present	Events Present	Events Present
PASS	-	PASS	PASS

Pass Criterion:

The pass criterion is detection of spiked CD45-/EPCAM+ SKBR3 cells at a concentration of 10000 cells/mL within the CTC-TVT on day 6.

Comments:

3 separately stained tests were performed at each of the time points.

Signature of Quality Control Manager



Date: 2018-04-03