

WO-00198: CT TotiCyte 200ml (lot 21804251)
CERTIFICATE OF ANALYSIS



Certificate version: 21804251.1
Issue date: 23 May 2018



WO-00198

CT TotiCyte 200ml

Product: CT TotiCyte 200ml
Product code: CT-TC-4310V01-200ML
Lot code: 21804251
Expiration date: 28 February 2019
Primary packaging material: Glass

Test	Method	Specification	Result
Sterility	Tested for bacterial sterility using ThermoFisher Scientific's VersaTrek system.	Sterile - Free from Bacterial Contamination	Pass
Endotoxin	ELISA-based Pyrodetect System Monocyte Activation Test (MAT); Merck©	Endotoxin and Pyrogen-free	Pass
Vitality	TotiCyte is added in an equal volume to umbilical cord blood (UCB) and the level of separation observed.	Expected Separation Observed	Pass
Volume	Calibrated filling method alongside 5% mass check.	Volume within 0.8% of stated	Pass

Storage: Product Stability Confirmed stored at Ambient Room Temperature 15 to 25 C, For 1 year from manufacture.

Signature:

P. Chand, Quality Manager

Release date: 11 May 2018