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ACN 100 319 122

CERTIFICATE OF ANALYSIS

QuantiFERON® - TB Gold: Single Patient Pack

(Cat No.: 0597-0201)

Lot Number: 0597-70261

Date of Expiry: 2010-05

DESCRIPTION:	The TB Antigen, Nil and Mitogen blood collection tubes are for use with the QuantiFERON®-TB Gold assay, which is a test of Cell Mediated Immunity for the detection of tuberculosis (TB) infection in humans. This simple and convenient blood test is designed to identify individuals who are infected with <i>Mycobacterium tuberculosis</i> complex (MTB) organisms. QuantiFERON®-TB Gold also provides an indication of the patient's general immune competence.
COMPOSITION:	<p>The TB antigen tubes contain synthetic peptides and heparin, which have been dried to the inner wall of the tubes.</p> <p>The Nil antigen tubes contain heparin, which has been dried to the inner wall of the tubes.</p> <p>The Mitogen tubes contain Phytohaemagglutinin and Heparin, which have been dried to the inner wall of the tubes.</p>
PRESERVATIVE:	Not applicable
PRECAUTIONS:	Not applicable
STORAGE TEMPERATURE:	4°C to 25°C

NUMBER OF COMPONENTS:

Component	Quantity per carton	Lot / Version Number	Expiry Date
TB Antigen tubes	1	L020901	2010-05
Nil Antigen tubes	1	L020901	2010-05
Mitogen tubes	1	L020901	2010-05



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QUALITY CONTROL TESTING:

TB Antigen tubes

Test	Criteria	Result
Visual examination	Clear coating visible on inside of tubes	Clear
Identity Test	Pass / Fail	Pass

Mitogen tubes

Test	Criteria	Result
Visual examination	Clear coating visible on inside of tubes	Clear
Identity Test	Pass / Fail	Pass

Nil Antigen tubes

Test	Criteria	Result
Visual examination	Clear coating visible on inside of tubes	Clear
Identity Test	Pass / Fail	Pass

This certifies that the results obtained for this batch of QuantiFERON®-TB Gold Single Patient Packs conform to the quality specifications set by Cellestis Quality Control.

Dr. Stephen Jones
Chief Technical Officer, Cellestis Limited
Date: 30 June 2009