

## Primary Cell Culture

# CERTIFICATE OF ANALYSIS

Product Code: IPT 200

Lot: 0509.2000.1

Expires: 02/2006

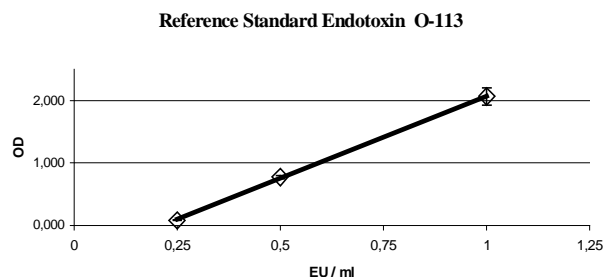
Ship on dry ice and store at  $-80^{\circ}\text{C}$  or below. This primary cell culture is for research only. Not for drug, household or other use. Not for in-vitro diagnostic or any therapeutic purposes. This lot is tested for sterility. It contains 5 blood donations that are checked for viral antigens as reported by officially authorized medical doctors:

Blood donation	differential hemogram	HIV	HAV	HCV	HBV	ParvoV
0509.2001	normal	negative	negative	negative	negative	negative
0509.2002	normal	negative	negative	negative	negative	negative
0509.2003	normal	negative	negative	negative	negative	negative
0509.2004	normal	negative	negative	negative	negative	negative
0509.2005	normal	negative	negative	negative	negative	negative

According to the EC directive 2000/54/EC this cell culture is a group 1 biological agent that is unlikely to cause human disease. Although, pyrogen testing according to Schindler et al. 2004 does involve a risk of exposure to this cell culture. The nature, degree and duration of workers' exposure are described in the manual of the Charles River test kit IPT 101. The guidelines for biosafety level 1 must be followed at least (Laboratory Biosafety Manual, 3rd edition, WHO). The employer must supply the competent authorities, at their request, with this information used for risk assessment.

The performance of the lot was tested with the Charles River IPT101 test components and the 2<sup>nd</sup> International Endotoxin Standard. For the Rabbit Equivalent Test (threshold assay) reconstitution of the lyophilized material of 4 vials of Control Standard Endotoxin Lot ET54601 in 3.2 ml saline and subsequently diluted 1: 16.0 (CV 2.1%) in saline yielded 0.5 EU/ml calibrated against OD450 of 0.5 EU Reference Standard Endotoxin (RSE) /ml.

Quantitative Pyrogen Assays with this primary cell culture require the use of RSE at dilutions from 0.25 to 1.0 EU/ml. The standard series performed the 2<sup>nd</sup> International Endotoxin Standard 94/580-SI resulted in a valid linear regression with a correlation coefficient above 0.99.




Dr. Walter Zwisler, Study Director, 1/18/06



Dr. Kilian Hennes, Site Manager, 1/18/06



Lot 0502.2000.1 was tested and complies with 2000/54/EC article (2)1.