

## **Certificate of Analysis**

<b>Cell count</b>	13.4 million per vial
<b>Viability</b>	95%
<b>CD3+</b>	52.6%
<b>CD19+</b>	10.5%
<b>CD14+</b>	17.1%
<b>CD11c+</b>	28.2%
<b>CD16+</b>	15.5%
<b>CD56+</b>	16.1%
<b>Sterility</b>	Negative for Bacteria, Yeast, and Fungi

### **Donor Information**

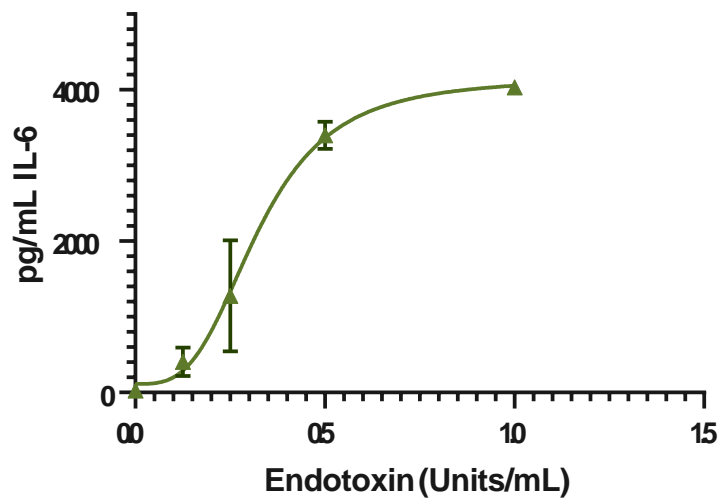
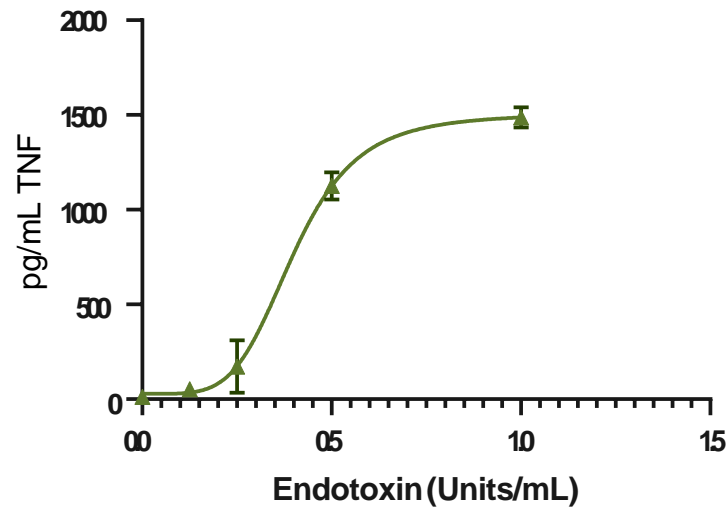
Prepared from 4 different individuals and pooled in equal numbers from each donor.

<b>Age</b>	<b>Gender</b>	<b>Race</b>
72	Male	Caucasian
60	Male	Caucasian
28	Male	Caucasian
64	Male	Caucasian

These cells are intended for use in the Monocyte Activation Test (MAT) for detection of pyrogens. Full validation of this method is the responsibility of the laboratory performing the testing. See the European Pharmacopoeia 6.7, monograph 2.6.30 Monocyte Activation test, for details.

Donors are tested for the blood borne pathogens HIV-1 and 2, Hepatitis B, Hepatitis C and HTLV-1 and are negative. Cells should still be handled as if potentially infectious following biosafety level 2 procedures

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Pooled PBMC were thawed and cultured in 96 well plate at  $4 \times 10^5$  cells per well in a volume of 100  $\mu$ L. Endotoxin standard was added at the indicated final concentration and culture medium was collected 20-24 hours after incubation at 37°C, 5% CO<sub>2</sub>. Concentration of IFN $\gamma$ , IL-1 $\beta$ , IL-6 and TNF $\alpha$  were measured using a Meso Scale Discovery kit.

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