Test Report

Toxicity testing of a material extract, Cytotoxicity Test

Test report number: ISO 201807-02438_engl

commissioned by:

Additive Manufacturing Technologies Ltd.

Alison Business Centre, 39-40 Alison Crescent
Sheffield S2 1AS, UK

CYTOX
biological testing of medical devices
Gottlieb-Keim-Straße 60
D-95448 Bayreuth, Germany

tel. +49-921-1511-254
fax +49-921-1511-255
mobile +49-179-5102577

info@cytox.de
www.cytox.de

Test material: Aug 03rd 2018

„AMT03 MJF-HP cube"" Polyamide-12 (PA-12) test specimen, colour black, post-processed 3D-printed by Multi Jet Fusion (MJF)

Test material received: Jul 18th 2018 Test performed: Aug 02nd 2018

Result:	**The „AMT03 MJF-HP cube"" Polyamide-12 (PA-12) test specimen, colour black, post-processed 3D-printed by Multi Jet Fusion (MJF) did not cause a cytotoxic effect.**

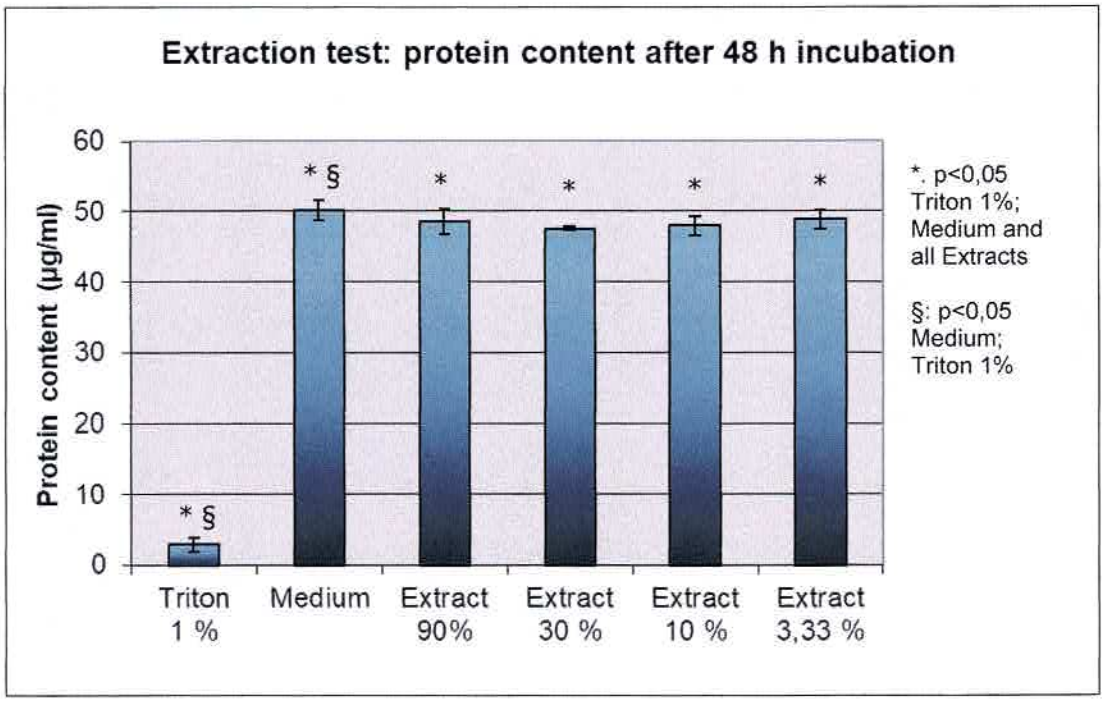
Description of the test procedure:

Normative References: ISO 10993-5 (2009); ISO 10993-1 (2010); ISO 10993-12 (2012)

The material was extracted for 24 h at 37°C and a partial presssure of 5 % carbon dioxide in extraction medium (DMEM medium with antibiotics, without fetal calf serum [FCS]). The material surface / extraction volume ratio was 3 cm^2 material per ml extraction medium. After extraction the extraction medium was sterile filtered and supplemented with sterile FCS (concentration of FCS in extraction medium: 10 %). The FCS-supplemented extraction medium was pipetted under sterile conditions on precultivated cells of the mouse fibroblastic cell line L929 and incubated for 48 h at 37°C and a partial pressure of 5 % carbon dioxide. The extract was tested in four dilutions (90 %, 30 %, 10 % and 3,3 %). Each dilution was tested in four parallel experiments.

Triton X 100 was used as a toxic control substance (concentration in the experiment: 1 % v/v). Cell culture medium was used as a non-toxic control. After the 48 h incubation period the protein content of the cell culture was determined by the method according to Bradford.

Results:



Result data µg/ml	Protein content n=4					
	Triton 1 %	Culture medium	Extract 90 %	Extract 30 %	Extract 10 %	Extract 3,3 %
Mean	2,98	50,09	48,57	47,51	47,94	48,89
Standarddev.	0,99	1,43	1,77	0,29	1,34	1,34

In the presence of Triton X 100 in the cell culture medium 6,0 % of the protein content compared to the negative control was reached. This value is within the valid range of 15 % protein content or less compared to the negative control.
Materials are considered cytotoxic, if the material extract leads to a protein content of the test cells of less than 70 % compared to the negative control. This was not the case in this test. The material extract did not show a cytotoxic effect.

Result:	**The „AMT03 MJF-HP cube"" Polyamide-12 (PA-12) test specimen, colour black, post-processed 3D-printed by Multi Jet Fusion (MJF) did not cause a cytotoxic effect.**

Explanatory notes:

none

Test performed by: _____

authorized by: _____
(Dr. D. Scheddin / CEO CYTOX)