



DIRECT CONTACT CYTOTOXICITY TEST REPORT – L08259
PREPARED FOR: INDENCO Dental Products, Inc.
PERPARED BY: MICROMED LABORATORIES, INC.

Summary of Test Report

Identification and Results Summary

File Number: L08259
 Test Requested: Direct Contact Cytotoxicity
 Results: See below
 Internal Procedures: TI/20012/04
 Test Guidelines: ISO 10993-5: 1992 Biological Evaluation of Medical Devices – Part 5 – Test for *in vitro* cytotoxicity
 Current USP <87>, Biological Reactivity Tests, *in vitro* C01196
 Client Code:

Identification of Samples:

Description of alloys: Orion Co 61.25,Cr 26.25,Mo 6.25, W 5.25, Si 1.0, Goldtech Bio 2000 Au 99.7%, In 0.2%, Z 0.1%
Lot Number: Orion™ 060511, Goldtech Bio 2000 1391253
Number of Samples: 2 alloys
 Comments: Rev. 01 product name change per client

Custody Summary

Samples Received: 5/12/2006 Samples received by: P. Iravani
 Test Start Date: 5/15/2006 Testing Technician: P. Iravani
 Test Completion Date: 5/17/2006 Report Generated by: P. Iravani

TEST RESULTS – CYTOTOXICITY

Sample/Control	Average Cytotoxic Grade	Reactivity
Orion™	0	None
Goldtech Bio 2000	0	None
Negative Control	0	None
Reagent Control	0	None
Positive Control	4	Severe

Test Description:

This study was conducted on test article (as described) to evaluate the presence of potential leachables which may induce toxic results *in vitro*. Results were recorded after 24 hours exposure. The test method was performed in compliance with the USP and/or applicable ISO guidelines. Positive controls, negative controls, reagent controls and the test article were prepared and in compliance with MicroMed Laboratories Test Instructions.

Confluent monolayers of L-29 Mouse Fibroblast cells (as recommended by ISO and USP) were prepared and challenged. These monolayers were graded using light microscopy. Cellular morphology was graded in accordance with the ISO acceptance criteria and USP guidelines (ref. ISO 10993-5 and current USP section 87).

Conclusion:

MicroMed Laboratories, Inc. project L08259 in accordance with above cited protocols.
 The tested alloys were found to be non-cytotoxic both scoring and equal zero reactivity.

Report reviewed by: B. Smith Date: 8/2/2006

Contact Information

For technical information regarding this study, please contact the MicroMed Laboratories, Inc. at (707) 782-0792.

* Orion™ of Indenco Dental Products, Inc.
 ** Goldtech Bio 2000 is a trademark of Argen Corp.