

CLIENT 10991



3D Systems Corporation  
26600 SW Parkway Avenue  
Wilsonville, OR 97070  
United States

**SUMMARY REPORT**

Test Article Name:	Figure 4 RUBBER-65A BLK
Physical Description:	Solid
Lot Number:	DT125-20200205F-1.3
Sample Code:	Not provided by Sponsor
Part Number:	20200325-RB65A_BioCompatibility
Expiration Date:	3/26/2022
Special Handling and/or Precautions:	None
Sterilization Data:	Non-Sterile
Storage Conditions:	Room Temperature
Final Intended Use:	Medical device

The Test Article “Figure 4 RUBBER-65A BLK” met the ISO 10993 testing guidelines specific to each type of test.

Testing Guidelines

ANSI/AAMI/ISO 10993-5:2009, *Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity*

Cytotoxicity – MEM Elution Test  
Pacific BioLabs Report Number: 20C0451H-M01G

ISO 10993-10:2010, *Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization*

Maximization Test for Delayed-Type Hypersensitivity in Hartley Guinea Pigs  
Pacific BioLabs Report Number: 20C0451H-X02G

Intracutaneous (Intradermal) Reactivity Test in New Zealand White Rabbits  
Pacific BioLabs Report Number: 20C0451H-X03G

## CONCLUSION

The test article “Figure 4 RUBBER-65A BLK” met the requirements of ISO 10993-5:2009 and ISO 10993-10:2010 guidelines.

## PACIFIC BIOLABS

Multiple Study Coordinator: Zuzana Karjala, Ph.D, RLATg, Senior Scientist

03 Jun 2020

X



I approve the content of this document.  
Signed by: Zuzana Karjala

:lc