

CLIENT 10991



3D Systems Corporation
26600 SW Parkway Ave.
Bldg 61
Wilsonville, OR 97070
United States

REPORT DATE

17 Mar 2020

SUMMARY REPORT

Test Article Name:	Figure 4 PRO-BLK 10
Physical Description:	Solid
Lot Number:	R19082036
Part Number:	20191001ProBLK10_01
Other Identifier:	Not provided by the Sponsor
Expiration Date:	10/1/2021
Special Handling and/or Precautions:	None
Sterilization Data:	Non-sterile
Storage Conditions:	Room Temperature
Final Intended Use/Application:	Medical Device

The Test Article “Figure 4 PRO-BLK 10” met the ISO 10993 testing guidelines specific to each type of test.

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: 19J0057H-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: 19J0057H-X02G

Intracutaneous (Intradermal) Reactivity Test in New Zealand White Rabbits
Pacific BioLabs Report Number: 19J0057H-X03G

CONCLUSION

The test article “Figure 4 PRO-BLK 10” met the requirements of ISO 10993-5:2009 and ISO 10993-10:2010 for tests as outlined above.

PACIFIC BIOLABS

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

18 Mar 2020

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

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