

CLIENT 10991



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REPORT DATE

17 Mar 2020

SUMMARY REPORT

Test Article Name: Figure 4 RUBBER-BLK 10
Physical Description: Solid
Lot Number: 2019091c-1.0
Part Number: 20191001_RbBLK10_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 RUBBER-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: 19J0056H-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: 19J0056H-X02G

Intracutaneous (Intradermal) Reactivity Test in New Zealand White Rabbits
Pacific BioLabs Report Number: 19J0056H-X03G

CONCLUSION

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

PACIFIC BIOLABS

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18 Mar 2020

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

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