



Hatano Research Institute (HRI)
Food and Drug Safety Center (FDSC)

Hatano Research Institute (HRI)/ Reference Materials (RMs) office produces positive and negative reference materials recommended for use under ISO 10993 for biological safety testing of medical devices, and distributes them to domestic and overseas users.

Reference Material Information Sheet

<RM-H>

Name of the RM:

High density polyethylene rod

Unique identifier of the RM:

RM-H (Lot no. H-221)

Reference material producer (name and address):

Hatano Research Institute (HRI), Food and Drug Safety Center (FDSC)

Address: 729-5 Ochiai, Hadano, Kanagawa 257-8523, JAPAN

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URL: http://www.fdesc.or.jp/fdesc_en/reference%20materials.html

Intended use:

RM-H is used to demonstrate a negative response in short-term implantation testing of medical devices. RM-H extracts show a negative response in cytotoxicity testing.

[Note]: In the quality inspection of this material, cytotoxicity tests instead of an in-vivo implantation tests were performed for the sake of animal welfare.

Shape and quantity:

Rod; diameter approx. 2 mm, length 100 mm, 10 rods/package

Storage condition:

Room temperature (avoid direct sunlight)

Production date:

July 11, 2022

Expiry period:

June 2029 (7 years after production)

[Note] The RMs are distributed directly from HRI/FDSC to users. Where RMs are resold by other organizations, HRI no longer has any responsibility for the quality of the RMs.

Method: Extraction with shaking in a CO₂ incubator (5%CO₂; 37±1°C)

Cell treatment:

Seeding cell number: 100 cells/well (6-well plate; 3 wells/concentration)

Concentration: 100%

Conditions: Placing in a CO₂ incubator (5%CO₂; 37±1°C) for 6 days

Fixing and staining: The cells were fixed with methanol and stained with Giemsa's solution.

Colony counting: The colonies formed in each well were counted with the naked eyes.

Relative plating efficiency (%): The relative plating efficiency was calculated by the following formula.

$$\frac{\text{Mean number of colony in 100\% extract group}}{\text{Mean number of colony in the blank group}} \times 100$$

Experimental period: September 20 to 27, 2022

Testing facility: Hatano Research Institute (HRI), Food and Drug Safety Center (FDSC)

Shigehiro Tachibana Sep. 28, 2022
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