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Test report

Report Number: SSMT-R-2026-04446-01 EN

Sample Name: Flame-retardant medical 3D mesh fabric

Study Title: In Vitro Cytotoxicity Test - MTT cytotoxicity test

Standard: ISO 10993-5: 2009

Test facility

Jiangsu Kerbio Medical Technology Group Co., Ltd.
C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

Changshu Zhengfangyi Manufacture Co., Ltd.

No. 198 Jiangxia Road, Meili Town, Changshu,

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Statement

1. Should any party wish to contest the findings of this report, a formal request for a review must be submitted within fifteen days of receipt of the report.
2. In the event of alterations or the absence of a special test seal, the report is considered invalid.
3. In the event that the signatures of the preparer, reviewer, and issuer are absent, the report is considered invalid.
4. For client-submitted samples, this laboratory assumes liability solely for sample reception.
5. The report may not be copied in part without the approval of the agency to ensure that the report is not partially extracted.
6. The test is conducted in the sub-facility, which is located at the following address: No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China.

Summary

This test evaluated the in vitro cytotoxicity of the test article by co-culturing L-929 cells with the test sample extract.

Well-grown L-929 cells were incubated with the sample extract at 37℃ in 5% CO_2 for 24 hours. Cell morphology was observed, and the cytotoxicity was determined by the MTT assay.

Test results were as follows: Cells in the negative control group exhibited normal morphology and good adherence; cells in the positive control group barely adhered and existed as suspended dead cells. The cell survival rate of the 100% sample extract was 84.4%, corresponding to Grade 0.

Under the conditions of this test, the extract of the test article did not show potential toxicity to L-929 cells.

Study Confirmation and Signature

Sample Received Date	2026.08.12
Experimental Starting Date	2026.08.17
Experimental Completion Date	2026.08.21

Editor Bella Pi 2026.08.31
Date

Reviewer Hanye Tao 2026.08.31
Date

Approver Lukas Gao 2026.08.31
Date

Jiangsu Kerbio Medical Technology Group Co., Ltd.

1. Purpose

The purpose of the study is to evaluate the risk of the sample to induce biological response of L-929 cells.

2. Reference

ISO 10993-5: 2009 Biological evaluation of medical devices Part 5: Tests for In Vitro Cytotoxicity

3. Sample Information

Table 1 Test Sample

Sample name	Flame-retardant medical 3D mesh fabric
Batch	/
Model	/
Specification	W403
Sample Material	100% polyester
Physical State	Solid
Sterilization Status	Non-sterile
Storage Condition	Room temperature
Manufacturer	Changshu Zhengfangyi Manufacture Co., Ltd.
Address	No. 198 Jiangxia Road, Meili Town, Changshu,
Note: Sample information was provided by sponsor and the sample photo is shown in Appendix.	

Table 2 Negative Control Sample

Name	High density polyethylene
Manufacturer	Alfa Aesar
Specification	1.6 mm thick, 300*300 mm
Batch	S16G044
Physical State	Solid
Storage Condition	Room Temperature

Table 3 Positive Control Sample

Name	Zinc diethyldithiocarbamate (ZDEC)
Manufacturer	Tokyo Into Industrial Co., Ltd.
Specification	25 g
Batch	3F84O-OL
Physical State	Solid
Storage Condition	Room Temperature

Table 4 Blank Control

Name	MEM complete medium (Add 10% fetal bovine serum and 1% penicillin-streptomycin mixture)
Physical State	Liquid
Storage Condition	2-8 ℃

4. Test System

4.1. Selection of Test System

L-929 cells (NCTC clone 929: CCL 1, American Type Culture Collection [ATCC]) were used in this study.

4.2. Justification of Test System

L-929 cells are used for cytotoxicity studies because they are demonstrated sensitivity to extractable cytotoxic articles.

The test article was extracted with a solvent and administered into the test system. This method was recommended in the standard.

5. Instruments and Reagent

5.1. Instruments

Vertical pressure steam sterilizer (SSMT-446)

Automatic cell counter (SSMT-2119)

CO_2 incubator (SSMT-279)

Biological microscope (SSMT-278)

Clean bench (SSMT-028)

Bench type low speed centrifuge (SSMT-048)

Constant temperature vibrator (SSMT-808)

Electronic balance (SSMT-1190)

Steel straight scale (SSMT-072)

Microorifice plate fast reading vibrator (SSMT-976)

Microplate spectrophotometer (SSMT-651)

Pipettor (SSMT-793, SSMT-2104, SSMT-2107, SSMT-2109, SSMT-2112)

5.2. Reagents

Table 5 Reagents

Name	Supplier	Lot
FBS	Cell-Box	2025112101
MEM medium	BasalMedia	C211407
Trypsin	Biosharp	35925004CJ
Penicillin, Streptomycin sulfate	Solarbio	2600010002
PBS	Beijing Lanjie Ke Technology Co., Ltd.	00926968AG
MTT	Beyotime	Z949B241106
Isopropyl alcohol	Shanghai Lingfeng Chemical Reagent Co., LTD.	20260107

6. Test Method

6.1. Sample Preparation

The test samples were used for testing after sterilization. Perform aseptic operation. Extract the sample according to the ratios and conditions specified in the table below. After extraction, check the changes in the extract and store it at room temperature. The extract shall be used for testing within 24 hours. The extracts were not filtered, centrifuged or diluted. No pH adjustment.

Table 6 Sample preparation

Aseptic sampling			Aseptic agitation extraction in inert container				Final extract
Sampling manner		Actually sampling	Extraction vehicle	Extraction ratio	Vehicle volume	Condition	Clear or not
Test article	Random sampling	60.0 cm^2	MEM complete medium	3 cm^2 : 1 mL	20.0 mL	37 °C, 72 h	Clear
Negative	Random sampling	90.0 cm^2		3 cm^2 : 1 mL	30.0 mL		Clear
Positive	Random sampling	0.03 g		/	30.0 mL		Clear
Blank	/	/		/	90.0 mL		Clear

6.2. Test Procedure

Aseptic procedures were used for handling cell cultures.

L-929 cells were cultured in MEM medium (10% FBS, Penicillin, Streptomycin) at 37°C with 5% CO_2. Cell cultures were removed from culture dishes by enzymatic digestion (0.25% trypsin containing EDTA) and the cell suspension was centrifuged (200 g, 3 min). The cells were then resuspended in culture medium and the cell suspension was adjusted at a density of 1×10^5 cells/mL.

The suspended cells were dispensed at 100 µL per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37°C) for 24 hours. Check cell morphology to verify that cells form a half-confluent monolayer.

Then aspirate culture medium from the cells. Per well, add 100 µL of treatment medium containing either the appropriate concentration of sample extract (100%, 75%, 50%, 25%), the negative control (100%) , the positive article (100%), the blank control. The 96-well plate was incubated at 37°C in cell incubator of 5% CO_2 for 24 hours. Six replicates were used for each concentration of test sample extracts or controls.

After 24 hours treatment, the 96-well plate was removed, examine the plate under a phase contrast microscope and then carefully remove the culture medium from the plates. 50 µL of the MTT solution (1 mg/mL) was added to each well and the plate was further incubated for 2 hours in the incubator at 37 °C. Then the MTT solution was discanted and 100 µL of isopropanol were added in

each well. Sway this plate and subsequently transfer it to a microplate reader to read the absorbance at 570 nm (reference wavelength 650 nm).

6.3. Statistical Method

Mean±standard deviation ($\bar{x}$±s)

$$Viab.\% = \frac{100 \times OD_{570\,e}}{OD_{570\,b}}$$

Where: OD_{570e}——is the mean value of the measured optical density of test sample/negative control/positive control;

OD_{570b}——is the mean value of the measured optical density of the blanks.

6.4. Observation of the Cell Morphology

Table 7 Observation of the cell morphology

Grade	Conditions of all cultures
0	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
1	Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Not more than 50 % of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; not more than 50 % growth inhibition observable.
3	Not more than 70 % of the cell layers contain rounded cells or are lysed; cell layers not completly destroyed, but more than 50 % growth inhibition observable.
4	Nearly complete or complete destruction of the cell layers.

7. Evaluation Criteria

The lower the Viab.% value, the higher the cytotoxic potential of the test item is.

If viability is reduced to < 70 % of the blank, it has a cytotoxic potential.

The 50 % extract of the test sample should have at least the same or a higher viability than the 100 % extract; otherwise the test should be repeated.

The Viab.% of the 100% extract of the test article is the final result.

8. Test Results

No contamination was observed in the cell culture system during the test, and the cells maintained good growth status with no abnormal morphological changes. The cell viability of the 50% extract of the test sample was higher than that of the 100% extract. The cell viability of the 100% extract of the test sample was taken as the final result, which was 84.4%, as shown in Table 8.

Table 8 Results of the cell vitality

Group	$\bar{x}\pm s$	Viability%	The morphology of the extracted cells was observed under the microscope
Blank control	0.706±0.036	100.0	0
Negative control	0.686±0.038	97.2	0
Positive control	0.025±0.001	3.5	4
100% test article extract	0.596±0.014	84.4	0
75% test article extract	0.612±0.044	86.6	0
50% test article extract	0.671±0.043	95.0	0
25% test article extract	0.691±0.046	97.8	0
Quality check	The mean OD_{570} of blanks is ≥ 0.2. The deviation between the mean of blanks on the left side (Row 2) and the right side (Row 11) of the 96-well plate and the mean of all blanks is 2.5%, which does not exceed 15%. The test meets the acceptance criteria.		

9. Conclusion

Under the conditions of this study, the extract of the test article did not show potential toxicity to L-929 cells.

10. Deviation Statement

This test was performed in full compliance with the Standard Operating Procedures (SOPs), with no deviations affecting the validity of experimental data.

11. Disclaimer

The test results contained in this report are solely based on the samples and related information provided by the client (including but not limited to sample identification, physical state, standard surface area/thickness, testing requirements, etc.). Should the validity of the results be compromised due to incomplete, inaccurate, or deviant information supplied by the client, this institution shall not bear any responsibility.

12. Records

All original records and the final report related to this test are archived at the Archives of Jiangsu Kerbio Medical Technology Group Co., Ltd.

13. Appendix

Sample photo

