

T:021-61152161, 60645151 F:021-64951517 中国.上海.徐汇区宜山路 889 号 3 号楼 7 楼 7/F, the 3rd Building, Yishan Road , Xuhui District, Shanghai, China 200233

Page 1 of 5

Test Report Date: 13th Jul. 2020

Client name: JIANGSU EYOUNG MEDICAL DEVICES CO.,LTD

Client address: NO.1 DONGTANG ROAD, ZHENGLU TOWN, TIANNING COUNTY, CHANGZHOU

CITY, JIANGSU PROVINCE

Assignment ID: 14A2002503

Sample No.: 14S20008009-02

Report on the submitted sample identified by the client as below:

Product Name Disposable Medical Face Mask

Quantity Received 50pcs

Batch No. 20200503

Manufacturer JIANGSU EYOUNG MEDICAL DEVICES CO.,LTD

Sample Receiving Condition Room temperature

Sample Receiving Date 26th May.2020

Testing Period 11th Jun.2020 –12th Jun.2020

Test Requested, Test Method and Test Results:

Please refer to the following page(s), Attachment 1.

The above sample was submitted and identified by the client. The test was carried out by SGS subcontractor certified ISO17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.

Signed for and on behalf of SGS

Racy Linspection & Testing Services
33
Life Science Quality Assurance

Authorized Signature

的社会的发展。 大學校園专用章

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and for electronic format documents, subject to Terms and Conditions for Electronic Documents at <a href="http://www.sgs.com/en/Terms-and-Conditions/Terms-and-Condi



Client name: JIANGSU EYOUNG MEDICAL DEVICES CO.,LTD Client address: NO.1 DONGTANG ROAD, ZHENGLU TOWN, TIANNING

COUNTY, CHANGZHOU CITY, JIANGSU PROVINCE

Assignment ID: 14A2002503 Sample No.: 14S20008009-02

Page 2 of 5

Attachment 1: Test for in vitro cytotoxicity (MTT cytotoxicity test)

SUMMARY

An in vitro cytotoxicity study was conducted to assess the potential for cytotoxicity of the test article: Disposable Medical Face Mask, based on the International Organization for Standardization ISO 10993-5:2009: Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity; ISO 10993-12:2012: Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials.

Four concentrations (100%, 75%, 50%, and 25%) of the test article extracts, the blank, 100% of the negative control and the positive control were prepared using Minimum Essential Medium (MEM) supplemented with 10% fetal bovine serum. The semi-confluent monolayers of L-929 mouse fibroblast cells were incubated with the test extract, the blank and two controls in a 96-well microplate respectively at 37°C under the condition of 5% CO2. After 24 h, the MTT colorimetric assay was employed and the plate was read on a microplate reader at 570 and 650nm. Then the viability of cells was calculated.

Under the conditions of this study, the viability of 100% extract of the test article was 83%. It can be considered that the test article extracts had not a cytotoxic potential.

MATERIALS

The test article provided by the sponsor was identified and handled as follows:

Test Article: Disposable Medical Face Mask

Sterilization Status: Sterile

Storage Conditions: Room temperature

Extract Vehicle: GIBCO's Minimum Essential Medium supplemented with L-glutamine

and 10% fetal bovine serum.

Test Extract Preparation: According to the statement of the sponsor, the absorption capacity was

> 12ml/one piece [Volume of extraction vehicle to 3.3g of the test sample]. Based on the ISO 10993-12:2012, the ratio of 0.1g:1 ml (Weight of the

test sample to volume of extraction vehicle), 3.3g of the whole test articles were covered with 33 ml extraction vehicle, then added an

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone \$64,559,567,143,65121 3rd Building No.889 Yishan Road Xuhui District, Shanghai, China 200233 t(86-21)61152197 f(86-21)64951517 www.sgsgroup.com.cn 中国上海徐汇区宜山路889号3号楼 邮编: 200233 t(86-21)61152197 f(86-21)64951517 e sgs.china@sgs.com



Client name: JIANGSU EYOUNG MEDICAL DEVICES CO.,LTD
Client address: NO.1 DONGTANG ROAD, ZHENGLU TOWN, TIANNING
COUNTY,CHANGZHOU CITY, JIANGSU PROVINCE

Assignment ID: 14A2002503 Sample No.: 14S20008009-02

Page 3 of 5

additional 12ml of extraction vehicle under aseptic conditions for preparing the test extract at 37 $^{\circ}$ C for 24 hours with continuously agitation during extraction. The extract was used immediately after extraction.

Blank Preparation: The extr

The extraction vehicle not containing the test sample, retained in a vessel identical to that which holds the test article and subjected to conditions identical to those to which the test sample is subjected during its

extraction.

Negative Control Preparation: Current SBRTC negative control, the ratio of 3 cm² high-density

polyethylene: 1 ml (surface area of the test article to volume of extraction

vehicle) was used and extracted at 37°C for 24 hours.

Positive Control Preparation: Current SBRTC positive control, the ratio of 6 cm² Polyurethane film

containing 0.1% zinc diethyldithiocarbamate (ZDEC): 1 ml (surface area of the test article to volume of extraction vehicle) was used and extracted

at 37 °C for 24 hours.

Condition of Extracts: All the extracts of the test and controls were clear and without any

special treatments.

METHODS

Test System Management:

Mouse fibroblast cells (L-929, from the cell bank of Shanghai Institutes for Biological Sciences), were cultured in MEM with L-glutamine supplemented with 10% fetal bovine serum at 37 $^{\circ}$ C in a gaseous environment of 5% carbon dioxide (CO₂). A 96-well microplate method was employed for the MTT colorimetric assay. Each well was seeded 100 µL suspension of 1×10⁴ cells, and incubated at 37 $^{\circ}$ C in 5% CO₂ atmosphere for 24 hours prior to use.

Experimental Procedure:

检验检测专用章 Inspection & Testing Services

After incubation, the growth medium was replaced with 100 µL four concentrations (100%, 75%, 50%, and 25%) of the test extract, 100% of the negative control and the positive control, the blank (row 2 and

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic former documents, studied to Ferms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-and-Conditions/Terms-and-Conditions/Terms-appx. Attention is drawn to the limitation of liability, identification and jurisdiction issues defined thierein. Any policy of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The company is soon responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full whiteof prior written approval of company. Any unauthorized alteration forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/ Inspection report & certificate, please contact us at telephone. 143, 6 5 1 2 2 or email: CN.Doccheck@sgs.com
3*** Building No.889 Yishan Road Xuhui District, Shanghai, China 200233 t(86-21)61152197 t(86-21)64951517 www.sgsgroup.com.on
中国上海徐区区宜山路 889 号 3 号楼 邮编: 200233 t(86-21)61152197 t(86-21)64951517 e sgs.china@sgs.com



Client name: JIANGSU EYOUNG MEDICAL DEVICES CO.,LTD
Client address: NO.1 DONGTANG ROAD, ZHENGLU TOWN, TIANNING

COUNTY, CHANGZHOU CITY, JIANGSU PROVINCE

Assignment ID: 14A2002503 Sample No.: 14S20008009-02

Page 4 of 5

11) respectively. Six replicates were prepared for each group. The 96-well plate was incubated at 37 [°]C in 5% CO₂ for 24h.

After 24 h treatment, the culture medium was removed carefully from the plates. 50µL of the MTT (Sigma, 1mg/mL) solution was then added to each test well and the plates were further incubated for 2 h at 37 °C in a 5% CO₂ atmosphere. Then the MTT solution was removed and 100µL isopropanol per well was added and shake for 10 min gently. The plate was read on a microplate reader at 570nm (reference wavelength 650nm). The viability of the cells was calculated according to the formula below:

Viab.%= 100 × OD_{570e}/OD_{570b}

Where

OD_{570e} is the mean value of the measured optical density of the extracts of the test sample;

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

A test meets acceptance criteria if the left and the right mean of the blanks do not differ by more than 15% from the mean of all blanks. If the viability of the test sample was reduced to <70% of the blank, it had 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.

RESULTS

Group	The optical density (570nm-650nm)	Viab.%
100% of the negative control	0.804±0.033	100
100% of the test extract	0.663±0.019	.5 83 5 5
75% of the test extract	0.705±0.018	88
50% of the test extract	0.732±0.024	92
25% of the test extract	0.760±0.033	95
100% of the positive control	0.038±0.006	5 65 500
The blank (row 2)	0.797±0.048	30 5 13 CG G
The blank (row 11)	0.802±0.051	5 56 5 5 55

Note: n=6

The mean value of optical density of the blank was 0.800±0.047; both the left (row 2) and the right (row 11) mean of the blanks were less than 15% from the mean of all blanks.

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms

Attention: To check the authenticity of testing/ Inspection report & certificate, please contact us at telephone 166-799/8907 1443 6 5 1 2 3 or email: CN_Doccheck@sgs.com
3° Building No.889 Yishan Road Xuhui District, Shanghai, China 200233 1(86-21)61152197 1(86-21)64951517 www.sgsgroup.com.cn
中国上海统区官山路 889 号 3 号楼 邮编:200233 1(86-21)61152197 1(86-21)64951517 e sgs.china@sgs.com



Client name: JIANGSU EYOUNG MEDICAL DEVICES CO.,LTD Client address: NO.1 DONGTANG ROAD, ZHENGLU TOWN, TIANNING COUNTY,CHANGZHOU CITY, JIANGSU PROVINCE

. ID 4440000500

Assignment ID: 14A2002503 Sample No.: 14S20008009-02

Page 5 of 5

CONCLUSION

Under the conditions of this study, the viability of 100% extract of the test article was 83%. It can be considered that the test article extracts had not a cytotoxic potential.

PHOTOGRAPH OF THE TEST ARTICLE



Remark: Results and conclusions apply only to the test article tested provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.

***End of Report ***

Unless otherwise agreed in writing, titls document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format becament, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, identification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The company's soil responsibility is, to its Clienty and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This documents. This documents. This documents. This documents when the full of the full of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this fast report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.