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Test Report

Date: 18th May. 2016

Client name: SHIJIAZHUANG HONGRAY GROUP CO., LTD.

Client address: SOUTH TONGDA RD.,EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

Assignment ID: 14A1601107

Sample No.: 14S16004014

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

Product Name	Nitrile Glove
Order No.	1370020
Quantity Received	20pcs
Sample Receiving Condition	Room temperature
Sample Receiving Date	23rd Mar.2016
Testing Period	25th Apr.2016 –27th Apr.2016

Test Requested, Test Method and Test Results:

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

The test was carried out by SGS subcontractor certified IS0 17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.

Signed for and on behalf of SGS
Jessie Xu
Life Science Quality Assurance
Authorized Signature

Attachment 1: Test for in vitro cytotoxicity (Agar diffusion test)

SUMMARY

An in vitro cytotoxicity study was conducted to assess the potential for cytotoxicity of the test sample: Nitrile Glove, based on the International Organization for Standardization ISO 10993-5:2009: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.

The test sample, negative control and positive control were prepared in appropriate size. Each sample was placed in contacted with the surface of an agar layer overlaying a monolayer of L-929 Mouse Fibroblast cells which were stained with neutral red vital stain at the bottom of the plate. For 24h incubation, the cells were evaluated with the general morphology, vacuolization, cell lysis and membrane integrity under and around the sample, the grade of cell reactivity was evaluated on 0~4 from none to Severe.

Under the conditions of this study, the test sample had slight cell reactivity. The negative control and the positive controls performed as anticipated.

MATERIALS

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

Test Sample:	Nitrile Glove
Storage Conditions:	Room temperature
Cell culture medium:	GIBCO's Minimum Essential Medium, supplemented with 10% calf serum and 1% L-glutamine.
Test Sample Preparation:	According the requirement of the sponsor, the test articles were sterilized by ethylene oxide two weeks before the treatment. The test sample with inside surface was prepared to a round sheet in 10mm diameter for testing.
Negative Control Preparation:	High-density polyethylene sheet, as the same size as the test sample.
Positive Control:	Polyurethane film containing 0.1% zinc diethyldithiocarbamate (ZDEC), as the same size as the test sample.

METHODS

Test System Management:

Mouse fibroblast cells (L-929, from the cell bank of Shanghai Institutes for Biological Sciences), were propagated at 37 ℃ in sealed flasks containing GIBCO's MEM, supplemented with 10% calf and 1% L-glutamine. For this study, two Φ100mm plates was seeded 10ml suspension of $2.5x10^5$ cells per millilitre, and incubated at 37 ℃ for 24h in order to obtain a confluent monolayer of cells.

Preparation of Agar Overlay:

Equal amounts of double strength Minimum Essential Medium (2xMEM) and 3% agar were combined to form an MEM-agar mixture. 10ml of the MEM-agar mixture was then placed in the cell culture plates that had a confluent monolayer of cells, and allowed to solidify over the cells to form the agar overlay. 10ml freshly prepared neutral red vital stain was added gently to cover the entire solidified agar surface. The strong light was shield from for 15min.

Experimental Procedure:

Two replicate test samples, one negative control and one positive control were applied symmetrically to the surface of the agar of each of two plates with the edge of the samples approximately 15mm from the edge of the plate. After the application of the samples, the plates were placed in a 37 ℃ incubator, under 5% carbon dioxide in air and incubated for 24h.

Following incubation, the response of the vitally stained monolayer was evaluated with the general morphology, vacuolization, cell lysis and membrane integrity under and around the sample. The achievement of a numerical grade greater than 2 was considered a cytotoxic effect. Grading for cell reactivity was bases on the following criteria:

Grade	Reactivity	Description of reactivity zone
0	None	No detectable zone around or under specimen
1	Slight	Some malformed or degenerated cells under specimen
2	Mild	Zone limited to area under specimen
3	Moderate	Zone extending specimen size up to 1.0 cm
4	Severe	Zone extending farther than 1.0 cm beyond specimen

RESULTS

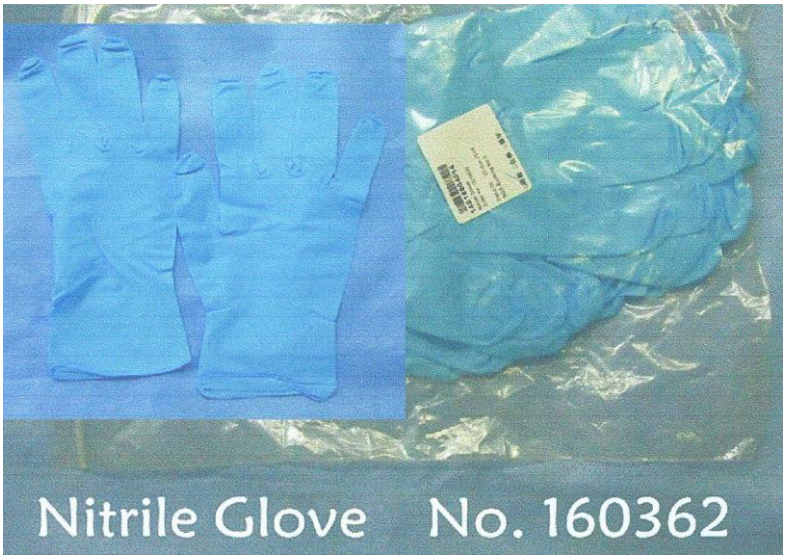
The cells of the test sample grew well and the cell membranes were integrity, and there were just few malformed and lysis cells under the specimen. All the cells of the negative control grew well and no abnormal reactivity was found. Most of the cells contacted with the positive sample became round and showed reactivity of cell lysis, vacuolization, and membrane unintegrity, the reactivity zone was extending father than 1.0 cm beyond the specimen. The grade of the test sample and each control were presented below:

Sample	Test Sample	Negative Control	Positive Control
Grade	1	0	4

CONCLUSION

Under the conditions of this study, the test sample had slight cell reactivity. The negative control and the positive controls performed as anticipated.

PHOTOGRAPH OF TEST SAMPLE



Remark: Results and conclusions apply only to the test sample 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 ***