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CNAS L0220

Number: GZHT02407734-S1

Digitally signed by Ciobanu Mircea
Date: 2021.04.22 14:02:16 EEST
Reason: MoldSign Signature
Location: Moldova

Report Ref:	GZHT02407734-S1	THIS IS TO SUPERSEDE REPORT NO. GZHT02407734 DATED Apr 14, 2021	
Date received :	Mar 31, 2021	**Date Issued:**	Apr 15, 2021

Company Name: **Address:**	NEOMATRIX SRL #121, 31 AUGUST 1989 STR MD-2012 CHISINAU, REPUBLIC OF MOLDOVA
Contact Name:	Sergiu Sirbu

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:		
End Uses	:	Non-Sterile Medical Face Mask
Ratings	:	Type IIR
Sample Name	:	Medical Face Mask
No. Of Sample	:	One (100 Pieces)
Size	:	175X97mm
Colour	:	Blue/White
Manufacturer	:	NeoMATRIX SRL
Buyer	:	NeoMATRIX SRL
Brand Name	:	MATRIX
Agent	:	Intertek Deutschland Gmbh
Standard	:	EN 14683:2019+AC:2019; ISO 10993-5:2009
Date received	:	Mar 31, 2021
Ref	:	Type No.: 3-Layers/3-Folds/with elastic Lot No.: 4840782288991/03-21 Product Registration Number: AMDM Nr.DM000274414

Test was conducted on specific items, at our client's request.

Approved by:

Charles Yang

Sr. Manager Senior Chemist

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QIN / hilaryxu

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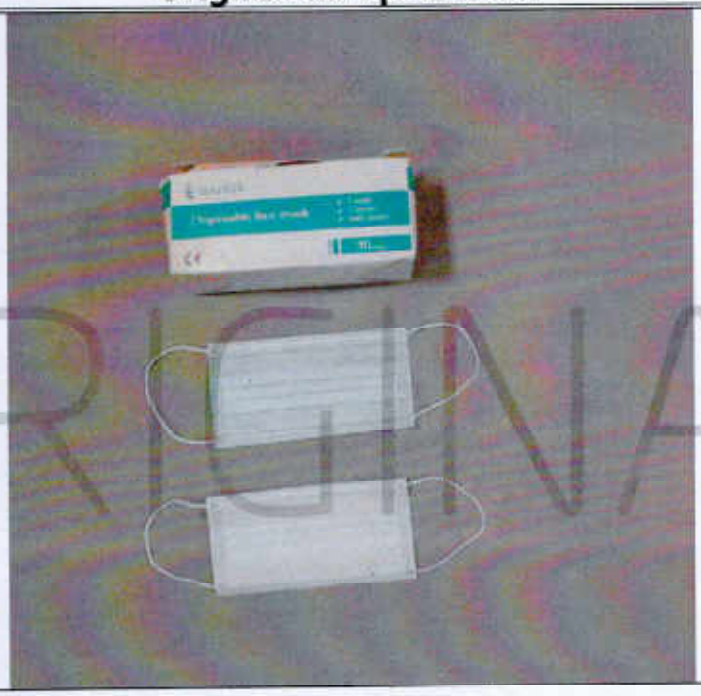
Original Sample Photo



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Summary of testing:

With reference to following standard:

- EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type IIR

Materials Used in The Submitted Sample Were Found To Comply With The Type IIR Requirements of EN 14683:2019+AC:2019 with respect to Microbial Cleanliness, Bacterial Filtration Efficiency, Differential Pressure and Splash Resistance Pressure tests.

Based on the test results of In Vitro Cytotoxicity Test, it can be concluded that under the experimental conditions, the test article Medical Face Mask have no potential toxicity to L-929 in the MTT method.

Approved by:

Sr. Manager Senior Chemist

QIN / hilaryxu

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Tests Conducted (As Requested By The Applicant)

1 Splash Resistance Pressure (*ISO 22609:2004*):
Synthetic Blood Surface Tension: 0.042 N/m, Distance Between Blow Head Front End And Target Area: 305 mm, Artificial Blood Volumes: 2 mL, Blood Pressure: 16.0 kPa, Velocity: 550 cm/s, Without Targeting-plate Used
Condition test specimens for a minimum of 4 hours in an environment of temperature (21±5) °C and relative humidity (85±5)% and conduct the test within 1 minute of removal from conditioning chamber.
Test Environment Condition: Temperature 22.1°C, Relative Humidity 80.2%

Tested Sample	Observation	Pass/Fail	Performance Requirement for Medical Face Mask
Specimen (1)	No penetration	Pass	Type IIR No Penetration at 16.0 kPa
Specimen (2)	No penetration	Pass	
Specimen (3)	No penetration	Pass	
Specimen (4)	No penetration	Pass	
Specimen (5)	No penetration	Pass	
Specimen (6)	No penetration	Pass	
Specimen (7)	No penetration	Pass	
Specimen (8)	No penetration	Pass	
Specimen (9)	No penetration	Pass	
Specimen (10)	No penetration	Pass	
Specimen (11)	No penetration	Pass	
Specimen (12)	No penetration	Pass	
Specimen (13)	No penetration	Pass	
Specimen (14)	No penetration	Pass	
Specimen (15)	No penetration	Pass	
Specimen (16)	No penetration	Pass	
Specimen (17)	No penetration	Pass	
Specimen (18)	No penetration	Pass	
Specimen (19)	No penetration	Pass	
Specimen (20)	No penetration	Pass	
Specimen (21)	No penetration	Pass	
Specimen (22)	No penetration	Pass	
Specimen (23)	No penetration	Pass	

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Tests Conducted (As Requested By The Applicant)

Specimen (24)	No penetration	Pass
Specimen (25)	No penetration	Pass
Specimen (26)	No penetration	Pass
Specimen (27)	No penetration	Pass
Specimen (28)	No penetration	Pass
Specimen (29)	No penetration	Pass
Specimen (30)	No penetration	Pass
Specimen (31)	No penetration	Pass
Specimen (32)	No penetration	Pass
Conclusion*:	**Accepted**	
* = An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.		

2 Differential Pressure (EN 14683:2019+AC:2019 Annex C):
Air flow: 8L/min, Test area diameter 25 mm, Test area: 4.9 cm^2.

Tested Sample	Result (Pa/cm^2)*					Performance Requirement for Medical Face Mask (Pa/cm^2)
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	
Location 1	42.4	46.2	41.2	43.3	48.8	Type IIR <60
Location 2	39.1	37.7	41.2	48.9	42.1	
Location 3	54.4	56.1	44.4	50.9	41.2	
Location 4	51.3	50.9	50.2	56.1	43.3	
Location 5	56.6	57.8	55.4	52.2	44.2	
Average	48.8	49.7	46.5	50.3	43.9	
* = All the locations were evenly taken from the main mask body.						

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Tests Conducted (As Requested By The Applicant)

3 Microbial Cleanliness

Test Method:
EN ISO 11737-1:2018 Sterilization of Health Care Products — Microbiological Methods — Part 1: Determination of a Population of Microorganisms on Products and EN 14683:2019+AC:2019 Medical Face Masks - Requirements and Test Methods Annex D

Test Condition:
Sample in unopened/closed/opened/wrapped with plastic sheet/original package/plastic bag/container
Number of test specimens: 5
The average plate count results of the negative controls: < 1 CFU

Test Procedure:
1. 5 test specimens are selected from the top, bottom and 3 randomly chosen masks.
2. Weigh each mask prior testing.
3. The full mask is aseptically removed from the packaging and placed in sterile 500 mL bottle containing 300 mL of extraction liquid.
4. The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
5. After extraction, 100 mL of extraction liquid is filtered through a 0.45 μm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filter in the same way and the filter plated on SDA for fungi enumeration.
6. The plates are incubated for 3 days at 30 ℃ and 7 days at (20 to 25) ℃ for TSA and SDA plate respectively.
7. Calculated the colonies of each agar plate.

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Tests Conducted (As Requested By The Applicant)

Calculation:
The total bioburden is expressed by addition of the TSA and SDA counts.

Test Result:

	Result			Limit (cfu/g)
	Weight of Specimen (g)	Total Bioburden Count (cfu/Mask)	Microbial Cleanliness (cfu/g)	
Specimen (1)	2.74	18	6.57	Type IIR ≤30
Specimen (2)	2.76	18	6.52	Type IIR ≤30
Specimen (3)	2.77	21	7.58	Type IIR ≤30
Specimen (4)	2.75	18	6.55	Type IIR ≤30
Specimen (5)	2.74	30	10.95	Type IIR ≤30

Remark: ≤ = Not more than
CFU = Colony Forming Unit

This test item was conducted in Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong.

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Tests Conducted (As Requested By The Applicant)

4 Bacterial Filtration Efficiency (BFE)

Test Method: EN 14683: 2019+AC: 2019 Annex B

Summary of Test Method:
A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. The bacterial aerosol is introduced into the aerosol chamber using a nebulizer and a culture suspension of Staphylococcus aureus. The aerosol is drawn through the medical face mask material using a vacuum attached to the cascade impactor. The six-stage cascade impactor uses six agar plates to collect aerosol droplets which penetrate the medical face mask material. Control samples are collected with no test specimen clamped in the test apparatus to determine the upstream aerosol counts. The agar plates from the cascade impactor are incubated for (20 to 52) h and counted to determine the number of viable particles collected.
The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Conditioning of the Specimens: 4 h at (21 ± 5) ℃ and (85 ± 5) % relative humidity

Test Condition:
Biological Aerosol: *Staphylococcus aureus* (ATCC 6538)
Testing side: Inside of the test specimen was facing towards the challenge aerosol
Test area: 78 cm^2
Flow rate: 28.3 L/min
The average plate count results of the positive controls: 2.0×10^3 CFU
The average plate count results of the negative controls: < 1 CFU
Mean particle size (MPS): 2.7 μm
Incubation condition: (37 ± 2) ℃ for (20 to 52) h
Number of test specimens: 5

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Tests Conducted (As Requested By The Applicant)

Test Procedure:

1. Preparation of the bacterial challenge: Dilute the culture in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
2. Deliver the challenge to the nebulizer using a peristaltic or syringe pump. Connect tubing to nebulizer and peristaltic pump and into the challenge suspension; purge tubing and nebulizer of air bubbles.
3. Perform a positive control run without a test specimen clamped into the test system to determine the number of viable aerosol particles being generated.
4. Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer.
5. Immediately begin sampling the aerosol using the cascade impactor. Adjust the flow rate through the cascade impactor to 28.3 L/m.
6. Time the challenge suspension to be delivered to the nebulizer for 1 min.
7. Time the air pressure and cascade impactor to run for 2 min.
8. At the conclusion of the positive control run, remove plates from the cascade impactor.
9. Place new agar plates into the cascade impactor and clamp the test specimen into the top of the cascade impactor, with the inside oriented toward the challenge as intended.
10. Repeat the challenge procedure for each test specimen and positive control sample.
11. Perform a negative control sample by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control sample.
12. Incubate agar plates at (37 ± 2) °C for (20 to 52) h.
13. Count each of the six-stage plates of the cascade impactor.
14. Total the counts from each of the six plates for the test specimens and positive controls. Calculate the filtration efficiency percentages.

Calculation:

The Bacterial Filtration Efficiency (BFE), was calculated as a percentage using the following equation:

$$\% \text{ BFE} = (C-T)/C \times 100$$

where,

C = Average plate counts total for test controls;
T = Plate count total for the test specimen.

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Tests Conducted (As Requested By The Applicant)

Test Result:

Tested Specimen	Result		Performance Requirement in EN 14683: 2019+AC: 2019 (% BFE)
	The Total Plate Count (T) (CFU)	Bacterial Filtration Efficiency (BFE) (%)	
Specimen (1)	0	>99.9	Type IIR: ≥ 98
Specimen (2)	3	99.9	
Specimen (3)	1	99.9	
Specimen (4)	1	99.9	
Specimen (5)	0	>99.9	

Remarks:

CFU = Colony Forming Unit

This item was conducted in Caipin Road, Guangzhou Science City, GETDD, Guangzhou, Guangdong.

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Tests Conducted (As Requested By The Applicant)

5 In Vitro Cytotoxicity Test (MTT Method)

Abstract

In this study, mammalian L-929 cells were cultured in vitro according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article.

The test articles and the control material were separately placed in MEM medium containing 10% fetal bovine serum, and extracted in a 37 ℃ incubator for 24 hours. After the end of the extraction, the cell culture medium in the 96-well plate (10^4 cells/well) cultured for 24 hours was removed and replaced with the corresponding extract, cultured in 37 ℃, 5% CO_2, >90% humidity for 24 hours. After the culture, the morphology and cell lysis of the cells were observed under the microscope, and the cytotoxicity of the test samples was determined by MTT assay.

The results showed that the cells in the blank control group and the negative control group (high density polyethylene) were well-formed throughout the experiment and showed no cytotoxic reaction. A severe cytotoxic response was shown in the positive control group (ZDEC). The 100% concentration of the test extract retained a normal appearance after 24 hours of incubation, and the cell viability was 85.8%. The data of each group met the acceptance criteria, and the results of this test were valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article have no potential toxicity to L-929 in the MTT method.

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Tests Conducted (As Requested By The Applicant)

1.0 Purpose

The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.

2.0 Reference

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

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12：2012)

3.0 Test and control articles

Groups	Test article	Negative Control Article	Positive Control Article	Blank Control
Name	Medical Face Mask	High Density Polyethylene Film	ZDEC	MEM medium, with addition 10% FBS
Manufacturer	NeoMATRIX SRL (#121, 31 August 1989 Str., MD-2012 CHISINAU, Republic of MOLDOVA)	Hatano Research Institute. FDSC	Sigma-Aldrich.	Hyclone
Size	Not provided	3 cm×10 cm (5 sheets)	25 g	500 ml
Model	Not provided	/	/	/
Lot Batch#	Not provided	C-161	BCBQ6847V	AF29549370

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Number: GZHT02407734-S1

Tests Conducted (As Requested By The Applicant)

Test Article Material	Not provided	/	/	/
Physical State	Solid	Solid	Solid	Liquid
Color	Blue/White	White	White	Pink
Packaging Material	Not provided	/	/	/
Sterilized or Not	No	No	No	Yes
Concentration	/	/	0.1%	/
Total Surface or weight	Not provided	/	/	/
Storage Condition	Room Temp.	Room Temp.	Room Temp.	4℃
Note: The information about the test article was supplied by the sponsor wherever applicable.				

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Tests Conducted (As Requested By The Applicant)

4.0 Identification and justification of test system

L-929 mouse fibroblast cells obtained from American Type Culture Collection (ATCC).

L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles. Also, the test article is extracted and administered in vitro to mouse fibroblast L929 cells through a solvent compatible with the test system, which is the optimal route of administration available in this test system as recommended in ISO 10993-5.

5.0 Equipment and reagents

5.1 Instruments

Vertical pressure steam sterilizer (SHB026), CO_2 Incubator (SHB002), Steel Straight Scale (SHB076), Electronic Balance (SHB016), Clean bench (SHB014), Multiskan Spectrum Microplate Spectrophotometer (SHB003), Bench type low speed centrifuge (SHB022), Inverted microscope (SHB005)

5.2 Reagents

MEM (Hyclone, AF29628620), FBS (Clark, JC65927), Penicillin-Streptomycin (Gibco, 2175429), Tryps in (Gibco, 2085461), PBS (Gibco, 8120015), MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bro mide) (Solarbio, 715S051), Isopropyl alcohol (Rhawn, RH246947)

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6.0 Experiment design and dose

6.1 Sample preparation

According to the table below, aseptic extraction of the test article sealed and incubated in MEM medium (10% FBS) at 37 ℃, 5% CO_2 and 60 rpm for 24 hours.

Groups	Sampling		Aseptic Extraction In Inert Container				Final Extract
	Sampling Manner	Actually sampling	Ratio	Extracts	Condition	pH	Clear or Not
Test article	Whole	570.0 cm^2	6 cm^2 : 1 ml	95.0 ml	37 ℃ 24 h	7.4	Clear
Negative Control	Random	60.0 cm^2	3 cm^2 : 1 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Positive Control	Random	0.02 g	0.1 g: 100 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Blank Control	/	/	/	20.0 ml	37 ℃ 24 h	7.4	Clear

The changes of the leaching solution was observed after extraction. No particulates or color changes were observed in pre- and post-extraction, the color and pH of the extraction solution did not change before and after use, and the pH value was 7.4, the status of the extract was shown in the figure below. The extraction solution and the pH value did not been adjusted, filtered, centrifuged, diluted and other processes before used.The extraction of the test article could be stored at 4℃ for no more than 24 h, but in our test, the test article extract were immediately be used after leaching.

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Vehicle	Time Observed	Extracts	Condition of Final Extracts		
			Color	Clear or Not	Particulates
MEM medium (10% FBS)	Before Extraction	Test article	Pink	Clear	None
		Negative Control	Pink	Clear	None
		Positive Control	Pink	Clear	None
		Blank Control	Pink	Clear	None
	After Extraction	Test article	Pink	Clear	None
		Negative Control	Pink	Clear	None

6.2 Test method

Aseptic procedures were used for handling cell cultures. L-929 cells were cultured in MEM medium (10% FBS, 1% Penicillin-Streptomycin solution) at 37 ℃ in a humidified atmosphere of 5% CO_2, then digested by 0.25% trypsin containing EDTA to get single cell suspension. 1 x 10^5 cells/ml suspension were obtained by centrifuging (1000 rpm, 5 min) and re-dispersing in MEM medium.

The suspended cells were dispensed at 100 μl per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37 ℃, >90% humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory. After 24 h incubation which made the cells grew to about 70% and form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 μl of extract of test article (100%、75%、50%、25%), control article, negative article and positive article respectively. The 96-well plate was incubated at 37 ℃ in cell incubator of 5% CO_2 for 24 h. Six replicates of each test were tested.

After incubation, observe the cell morphology first and then discard the culture medium. Add 50 μl MTT (1mg/ml) to each well and then incubated at 37 ℃ in a humidified atmosphere of 5% CO_2 for 2 hours. The liquid in each well was tipped out and 100 μl Isopropyl alcohol was added to each well to suspend the cell layer.

Evaluate the suspension above with a dual-wavelength spectrophotometer with the measurement wavelength at 570 nm.

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7.0 Statistical method

Mean±standard deviation ($\bar{x} \pm s$)

The cell cytotoxicity ratio = OD_{570} of test (or positive or negative) article group/ OD_{570} of blank control group ×100%.

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.

8.0 Evaluation criteria

8.1 The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated.

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

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

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

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Tests Conducted (As Requested By The Applicant)

9.0 Results of the test

9.1 Results of the cell morphology

Table 2 Observation of the cell morphology

Group	Before inoculation	Before treated with extract	24 h after treatment
Blank control	0	0	0
Negative control	0	0	0
Positive control	0	0	4
100% Test article extract	0	0	0
75% Test article extract	0	0	0
50% Test article extract	0	0	0
25% Test article extract	0	0	0

9.2 Results of the cell vitality

Table 3 Results of the cell vitality

Group	OD value								Viab. (%)
	1	2	3	4	5	6	$\bar{x}$	s	
Blank control	0.612	0.621	0.634	0.611	0.624	0.631	0.622	0.009	100.0
Negative control	0.609	0.611	0.616	0.613	0.621	0.630	0.617	0.008	99.1
Positive control	0.056	0.050	0.060	0.056	0.058	0.060	0.056	0.004	9.1
100% test article extract	0.517	0.525	0.530	0.517	0.560	0.553	0.534	0.018	85.8
75% test article extract	0.569	0.574	0.568	0.571	0.568	0.572	0.570	0.002	91.7
50% test article extract	0.579	0.583	0.577	0.587	0.595	0.593	0.586	0.007	94.2
25% test article extract	0.611	0.602	0.609	0.603	0.589	0.598	0.602	0.008	96.8

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TEST REPORT

Number: GZHT02407734-S1

Tests Conducted (As Requested By The Applicant)

10.0 Conclusion

Under the conditions of this study, the test article have no potential toxicity to L-929 cells

Remark: This test item is subcontracted to a CNAS accredited organization with Registration No.: L13034.

End of Report

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To : NEOMATRIX SRL
Attention : Sergiu Sirbu

Date : Apr 15, 2021

Re : Report Revision Notification

Labtest Report Number GZHT02407734 date APR 14, 2021

Please be informed that all the content recorded in the above captioned report will be void. This captioned report is now superseded by a revised Labtest Report, Number GZHT02407734-S1 , issued on Apr 15, 2021 .

Changes to the Report	Change to CNAS Report

Thank you for your attention

Approved by:

Sr. Manager Senior Chemist

INTERTEK TESTING SERVICES SHENZHEN LTD. GUANGZHOU BRANCH (10)

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