OXIGEN ANALİZ ÖZEL KONTROL LABORATUVARI

Çakmaklı Mah. Hadımköy Bağlantı Yolu Ufuk Plaza

No:57 K:1 D:8 34500 Büyükçekmece/İSTANBUL

INSPECTION AND ANALYSIS REPORT

Test
TS EN ISO/IEC 17025
AB-0953-T

AB-0953-T
2021-C-00191
02-2021

Report Number	: 2021-C-00191	Date of Report	: 05/02/2021
Purpose of Analysis	: Cytotoxicity Test		
Costumer name/addres	: DEXXON ENERJİ SAN VE TİC.A.Ş /Istanbul Vizyon Park Ofis Blokları Yeni Bosna Merkez Mah 29 Ekim Cad No:3 Plaza : 1 Kat : 8 No: 84 / İstanbul		
Name and identity of test item	: FFP2 NR Disposable Face Mask Without Valve		
Code of sample	: Lot: Dexxon Medical DXNMD-NRFM04 FFP2 NR		
Package of Sample/Quantity	: 3 Piece		
Date of receipt of test item	: 26/01/2021		
Date of Test/End of test	: 27/01/2021 - 03/02/2021		
Number of pages	: 6		

Analysis	Unit	Result	Limit Of Measurement	Recovery	Uncertainity of Meas.	Analysis Metod	Com.
1-*InvitroCytotoxicity Test		it is not Cytotoxicity				TS EN ISO 10993-5((Biologicalevaluation in medicaldevicesPart 5: Test for in vitrocytotoxicity TS EN ISO 10993-12 (Biologicalevaluation in medicaldevicesPart 12: Test samplepreparationand Reference Materials..	U

Explanation:

1. Experiment environment

CELL LINE:L929 (Mouse Fibroblast cell)

CultureMedium : DMEM+ L-Glutamin
Fetal Bovine Serum

Penisilin- Streptomisin

Blank : Sterile cell culture medium

NEGATIVE CONTROL: Polietilen Kryo Tüp + Cell

POSITIVE CONTROL: Natural RubberLatex+ Cell

2.METHOD OF APPLICATION

Extraction was performed according to TS EN ISO 10993-12 standard. The samples were placed in a waterbath at a rate of 50 rpm at 37ºC for 24 hours in a 10% serum-containing cellculture medium of the size specified in the standard. The extraction was then terminated and the extract obtained was used within 24 hours.

3.ANALYSIS METHOD

Qualitative Evaluation:

Cells were expected to become confluent by sowing 6 well plates.
Subsequently, the 37°C 5% CO2 sample was exposed to negative, positive control and sample extracts for 24 hours. After incubation, cells were microscopically examined ande valuated according to TS EN ISO 10993-5 standard.

Quantitative Evaluation:

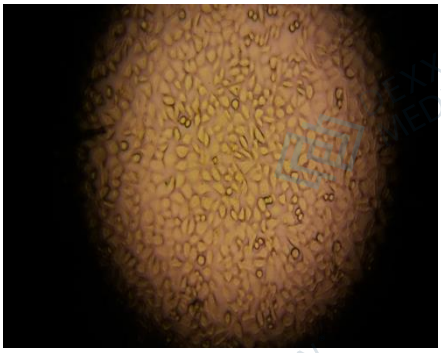
In the study, it was applied according to the "TS EN ISO 10993-5 / XTT Cytotoxicity Experiment" standard. The 96-well plate was counted as 100 / well and the cultured cells were incubated for 24 hours to provide 80% confluency. Subsequently, the cells were exposed to 1/1 - dilutions of the sample extract for 4 hours.
At the end of the process, 1 mg / mL XTT was added to the wells and the plates were incubated for 3 hours at 37 ° C in 5% CO2. The assay was terminated by the addition of isopropyl alcohol to the wells and the% viability values were calculated by measuring the color change in the plates (570-650 nm) spectrophotometer.

4. TEST RESULTS

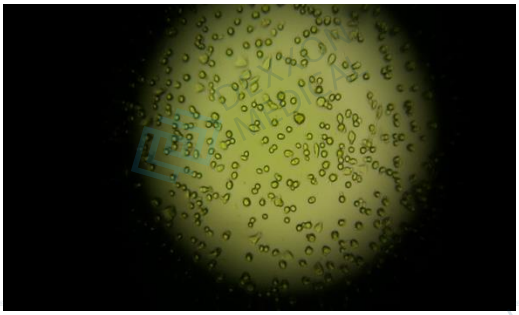
Qualitative Evaluation:

The qualitative evaluation was made according to Table 1 in TS EN ISO 10993-5 standard.

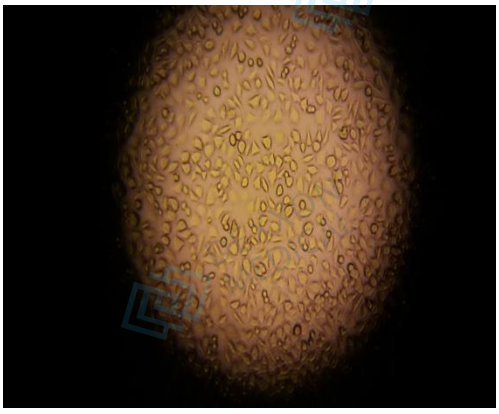
a.Negatif Kontrol



b. Pozitif Kontrol



c. Numune



Must No.	Test Material	Reaction	Situations of Cultures
1	Negative Control	0	Discreteendoluminalgranules, celldisruptionno, nodecrease in cellproliferation
2	Positive Control	4	Nearlyallcelllayers have been destroyed
3	Sample	0	Discreteintraoplasmagranules, no cell destruction, no decrease in cell proliferation

Quantitative Evaluation:

(TS EN ISO 10993-5 / XTT Cytotoxicity Test)

Table 2. XTT Test results

DILUTION RATIOS						
TEST NUMBER	**100%**	**75%**	**50%**	**25%**		
1. AGAIN	1,021	1,125	1,268	1,327		
2. AGAIN	0,995	1,117	1,287	1,324		
3. AGAIN	0,997	1,214	1,246	1,331		
AVERAGE	1,004	1,152	1,267	1,327		
POSITIVE CONTROL	**100%**	**75%**	**50%**	**25%**		
1. AGAIN	0,104	0,117	0,134	0,184		
2. AGAIN	0,109	0,121	0,140	0,169		
3. AGAIN	0,115	0,120	0,139	0,162		
AVERAGE	0,109	0,119	0,138	0,172		
Negative Control(%100)	**1.Again**	**2.Again**	**3.Again**			
%100 Ekstrakt	1,011	1,09	1,11			
AVERAGE	1,07					
Blank	**A2**	**A3**	**A4**	**A5**	**A6**	**A7**
	0,999	1,003	1,02	1,017	1,10	1,13
	H2	**H3**	**H4**	**H5**	**H6**	**H7**
	0,999	0,998	1,11	1,13	0,999	0,999
AVERAGE	1,04					

Viab.%=100 X OD450e/OD450b

OD450e : % 100 optical density of the sample extract

OD450b : Average value of optical density of blank

Test SampleViab.% : % 96

PozitiveControlViab.% :% 10

Negative ControlViab.% : %103

REVIEWS :

1.The test was carried out in accordance with the standard "TS EN ISO 10993-5 Biological evaluation of medical devices-Part 5: extrac or poreal cytotoxicity tests".

2.The effect of the extracts on the cells for qualitative evaluation was examined microscopically and evaluated by the qualitative morphological grading of the cytotoxicity of the extracts given in the standard "Table 1. Accordingly, the negative control showed no toxic effect on the cells (0), and the positive control showed toxicity as high as expected (4). Since the cytotoxic effect of the sample extracts was not toxic when examined, it wasevaluated as (0).According to the standard used, as indicated in table 1, the presence of a larger rating value of (2) is considered a cytotoxic effect.

3.The "TS EN ISO 10993-5 / XTT Cytotoxicity Experiment" wasused as the quantitative evaluation method and the obtained results (Table 2) were evaluated statistically. Results from the negative and positive controls used and test validity criteria are met.

In this experiment, the effects of 1/1 dilutions of sample extract on cells were examined; The complete dilution of extract from the sample (1/1) andviability was **96%**.

According to the standard used, this value is lessthan 70%, indicatingthatthere is nocytotoxic effect on thesampleextracts since there is a cytotoxicityindicator.

Report Number : 2021-C-00191 Date of Report : 05/02/2021

Chart1. Qualitative morphological grading of cytotoxicity of extracts

Degree	Reaction	Situations of Cultures
0	No	Discreteintraoplasma granules, no cell destruction, no decrease in cell proliferation
1	Very little	There are more than 20% of cells that are not round, poorly adherent, and contain few or no intracellular granules, or morphologicallyaltered, rarely destroyed cells, only slight growth inhibition can be observed
2	Light	Round cell number is less than 50%, nointraplosiongranules, observable cell inhibition is not more than 50%
3	Middle	The number of cells rounded or destroyed is not more than 70%, the cell layers are not completely degraded, the observable cell inhibition is more than 50%
4	Severe	Nearly all cell layers have been destroyed

(*) Analysis method is in scope of acreditation.
Evaluation:
Theabovementionedvalueswereddetermined as theresultof theinspectionandanalysis.
1.No part of thisanalyticalreport can be usedaloneorseparately. Unsignedandunsealedreportsaredefund.
2.Analysis resultsarevalidfortheabovesample
3.When necessary, "MeasurementUncertainty" and "Recover" informationaregiventogetherwiththeanalysisresults
4.Judicial andadministrativeproceduresto be usedforadvertisingpurposes. It can not be partiallyreproducedandpublishedwithoutpermission
5. Measurement uncertainty is applied in favor of the customer in Quantitative Analysis.
6. Decision Rule is not applied in microbiological analyzes.

Abbreviations: N.A: Not Detected A:Appropriate IA: Inappropriate AF: AssessmentFailedEVL :Evaluation

Çel Microbiology Unit Responsible
Havva Lamia Demir

Responsible of theDepartment of SampleAdmission
Kadriye ŞEREF

Approved by
05/02/2021
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Etikimza Süreç No : j0ms9un55mf7d686ca9f kodu ile www.oxigenanaliz.com adresinden doğrulayabilirsiniz.