

TEST REPORT N. 20/000177958

date of issue 15/05/2020

Customer ID 0083305

Messrs
NANOBIOTECH AR-GE
INOVASYON SAGLIK URUNLERI
YILDIRIM BEYAZIT MH.
ERCIYES TGB IDARE VE
KULUCKA 2, NO:65/5 -
MELIKGAZI
- KAYSERI - TURKEY
Turchia

Sample information

Acceptance number 20.508259.0001

Delivered by TNT Traco on 11/03/2020

Receiving Date 11/03/2020

Place of origin NANOBIOTECH AR-GE INOVASYON SAGLIK URUNLERI YILDIRIM BEYAZIT MH. ERCIYES TGB IDARE VE KULUCKA 2, NO:65/5 - MELIKGAZI - KAYSERI - TURKEY Turchia

Sample Description EFFICACY TESTING ACCORDING TO EN 14476 Human Coronavirus 229E
Sample: NANOKSIA - Lot : 19123051

Sampling information

Sampled by Customer

ANALYTICAL RESULTS

	Value/ Uncertainty	Unit of measure	LoQ	LoD	Start/end date of analysis	Op. units	Line
ON SAMPLE AS IT IS							1
VIRUCIDAL ACTIVITY:SUSPENSION TEST Met.: UNI EN 14476:2019	view attached report				12/03/2020- -13/05/2020	09	2

Operative units

Unit 09 : Via Fratta Resana PHARMA (TV)

Information provided by the client

Sampled by: Customer
Pick Address: NANOBIOTECH AR-GE INOVASYON SAGLIK URUNLERI YILDIRIM BEYAZIT MH. ERCIYES TGB IDARE VE KULUCKA 2, NO:65/5 - MELIKGAZI - KAYSERI - TURKEY Turchia
Description: EFFICACY TESTING ACCORDING TO EN 14476 Human Coronavirus 229E Sample: NANOKSIA - Lot : 19123051

Biologist responsible

Dott.ssa Federica Cattapan

Ordine nazionale dei biologi
Albo professionale n.045961 sez.ANum. certificato 18128093 emesso dall'ente
certificatore ArubaPEC S.p.A. NG CA 3, ArubaPEC
S.p.A., IT

- If not otherwise specified, the uncertainty is extended and has been calculated with a coverage factor $k=2$ corresponding to a probability interval of about 95%. - LoD is the detection limit and identifies a confidence interval of zero with a probability interval of about 99%. - LoQ is the limit of quantification. "n.d" is not detected and indicates a value inferior to the LoD. "traces (X)" means a value between LoD and LoQ, this value is indicative. "<x" or ">x" indicate inferior or superior to the measurement field of the test. - If not differently specified, the sums are calculated by lower bound criteria (L.B.). - In case of alteration of the sample the laboratory declines any responsibility on the results that can be influenced by the deviation in case the customer asks for the execution of the test anyway. - If the sampling is not carried out by the laboratory staff, the results obtained are considered referring to the sample as received and the laboratory declines its responsibility for the results calculated considering the sampling data provided by the Customer. The name and contact information of the Customer are always provided by the Customer. - If not differently specified the quantitative microbiological tests (excluded MPN) are performed on single repetition and two consecutive dilutions in accordance to ISO 7218:2007/Amd1:2013.

ATTACHMENT TO TEST REPORT 20/000177958

UNI EN 14476+A2:2019

Chemical disinfectants and antiseptics
Quantitative suspension test for the evaluation
of virucidal activity in the medical area
(phase 2, step 1)

ID Sample: 20.508259.0001

Sample description: Lot. No.: 19123051
Active substance: n.a.
Receiving date: 12/03/2020
Product appearance: liquid, colorless

Sponsor NANOBIO TECH ARGE INOVASYON SAGLIK URUBLERI YILDIRIM
Beyazit MH. Erciyes tgb Idare ve Kulucka 2 No:65/5
Melikgazi, Kayseri - Turke

METHOD

UNI EN 14476+A2:2019

EXPERIMENTAL CONDITIONS

- Test virus and number of passages:
Vaccinia virus, strain Ankara, ATCC-VR-1508 (passage n° 5) used as a surrogate virus for enveloped viruses (i.e. Coronavirus)
- Cell line and number of passages:
BHK-21-cl 13, IZS-Brescia for the propagation of *Vaccinia virus* (passage n° 93+5)
- Product test concentrations: 97%
- Diluent used for product test solution: Distilled water
- Appearance of product dilutions: Liquid and colorless
- Stability and appearance of the mixture during the procedure: Stable, without precipitates
- Interfering substance: Albumin Bovine 0,3 g/l (clean conditions)
- Contact time: 60 min ± 10 sec
- Test temperature: 20 °C ± 1°C
- Neutralization method: Filtration method with Microspin™ S400HR columns
- Growth medium: MEM 10% FCS
- Maintenance medium: MEM 2% FCS

TEST RESULTS

See tables n° 1 and 2.

CONCLUSIONS

According to UNI EN 14476+A2:2019, under the test conditions applied, the test product at concentration 97% resulted to have virucidal activity ($R \geq 4$) against Vacciniavirus.

Table 1: Results of the test UNI EN 14476+A2:2019 on Vacciniavirus

Vacciniavirus							
Test	Contact time	Interfering substance	Concentration	Virus titration (Log TCID50)	Reduction	Acceptance criteria	Result
Susceptibility (Control)	60 min	PBS	/	5,75 (CI95% = 0,328 → PASS)	/	/	/
Susceptibility (Test substance)	60 min	PBS	0,097%	5,875 (CI95% = 0,366 → PASS)	0,125 (CI95% = 0,491)	R < 1	PASS
Virus Titration	0 min	0,3 g/l bovine albumin	/	5,75 (CI95% = 0,444 → PASS)	/	/	/
	60 min	0,3 g/l bovine albumin	/	5,875 (CI95% = 0,366 → PASS)	0,125 (CI95% = 0,575)	R < 1	PASS
Reference Virus Inactivation	5 min	/	0,7%	3,875 (CI95% = 0,366 → PASS)	2 (CI95% = 0,818)	0,75 ≤ R ≤ 3,5	PASS
	15 min	/	0,7%	3,125 (CI95% = 0,366 → PASS)	2,75 (CI95% = 0,818)	2 ≤ R ≤ 4	PASS
Virucidal Activity	60 min	0,3 g/l bovine albumin	97%	≤ 1,5 (CI95% = 0 → PASS)	≥ 4,375 (CI95% = 0,366)	ACTIVE if R ≥ 4	ACTIVE
Efficiency of Product's Activity Suppression	30 min	0,3 g/l bovine albumin	97%	5,625 (CI95% = 0,25 → PASS)	0,25 (CI95% = 0,443)	R ≤ 0,5	PASS

* lowest apparently non cytotoxic dilution

Table 2: Raw Data UNI EN 14476+A2:2019 on Vacciniavirus

Vacciniavirus														
Test	Contact time	Interfering substance	Concentration	Virus dilution (Log ₁₀)										
				-1	-2	-3	-4	-5	-6	-7	-8	-9	-10	-11
Susceptibility (Control)	60 min	PBS	/	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4440 0000	0000 0000	0000 0000	0000 0000	0000 0000	/
Susceptibility (Test substance)	60 min	PBS	0,097%	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4440 0000	0000 0000	0000 0000	0000 0000	0000 0000	/
Virus Titration	0 min	0,3 g/l bovine albumin	/	/	4444 4444	4444 4444	4444 4444	4444 4440	4440 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
Virus Titration	60 min	0,3 g/l bovine albumin	/	/	4444 4444	4444 4444	4444 4444	4444 4444	4440 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
Reference Virus Inactivation	5 min	PBS	0,7%	/	4444 4444	4444 4444	4440 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
Reference Virus Inactivation	15 min	PBS	0,7%	/	4444 4444	4444 4000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
Virucidal Activity	60 mn	0,3 g/l bovine albumin	97%	/	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
Efficiency of Product's Activity Suppression	30 min	0,3 g/l bovine albumin	97%	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4000 0000	0000 0000	0000 0000	0000 0000	0000 0000	/

1 to 4 = virus detectable / 0 = no virus