MERIEUX NutriSciences

**CHELAB S.R.L.**

# 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<br>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<br>Ordine nazionale dei biologi<br>Albo professionale n.045961 sez.A |
| Num. 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 probabilty 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.



**END OF TEST REPORT**



CHELAB S.r.l. Socio Unico, Company subject to the direction and coordination of Mérieux NutriSciences Corporation

Head office: Via Fratta 25 31023 Resana, Italy Phone. + 39 0423.7177 / Fax + 39 0423.715058 www.merieuxnutrisciences.it

VAT nr. 01500900269, R.E.A Treviso n. 156079 Fully paid up € 103.480,00.

## 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 | NANOBIOTECH 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




Chelab S.r.l. - Socio Unico, Company subject to the direction and coordination of Mérieux NutriSciences Corporation
Head Office via Fratta 25, 31023 Resana, Italy phone +39 0423 7177 fax +39 0423 715058 e-mail contact.italy@mxns.com web site merieuxnutrisciences.com/eu
VAT n. IT 01500900269 R.E.A Treviso 156079 fully paid up € 103.480,00

**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 ≥ 4) against Vacciniavirus.




Chelab S.r.l. - Socio Unico, Company subject to the direction and coordination of Mérieux NutriSciences Corporation
Head Office via Fratta 25, 31023 Resana, Italy phone +39 0423 7177 fax +39 0423 715058 e-mail contact.italy@mxns.com web site merieuxnutrisciences.com/eu
VAT n. IT 01500900269 R.E.A Treviso 156079 fully paid up € 103.480,00

**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 |
| **Efficency 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





Chelab S.r.l. - Socio Unico, Company subject to the direction and coordination of Mérieux NutriSciences Corporation
Head Office via Fratta 25, 31023 Resana, Italy phone +39 0423 7177 fax +39 0423 715058 e-mail contact.italy@mxns.com web site merieuxnutrisciences.com/eu
VAT n. IT 01500900269 R.E.A Treviso 156079 fully paid up € 103.480,00

**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 | 4400 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 |
| **Efficency 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





Chelab S.r.l. - Socio Unico, Company subject to the direction and coordination of Mérieux NutriSciences Corporation
Head Office via Fratta 25, 31023 Resana, Italy phone +39 0423 7177 fax +39 0423 715058 e-mail contact.italy@mxns.com web site merieuxnutrisciences.com/eu
VAT n. IT 01500900269 R.E.A Treviso 156079 fully paid up € 103.480,00