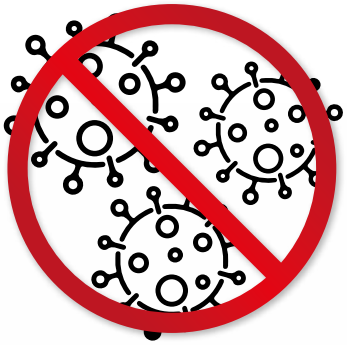
Bioxigen®

your best indoor air quality

English

2021



STOP
COVID-19

pure air

Il sistema che sanifica e deodorizza l'aria e le superfici
The system that sanitizes and deodorizes the air and the surfaces

Tested against COVID-19

DISTRIBUTOR IN VIETNAM:
BACH KHOA INTERNATIONAL EQUIPMENT JSC

bkic.vn | info@bkic.vn | +84 903 999 357

LabAnalysis
HIGH QUALITY CONTROLS

TECHNICAL REPORT

VIRUCIDAL ACTIVITY STUDY OF THE "MAIA" PRODUCT (UNI EN 16777:2019)

Technical Report N° D202101605

Customer:	SKILL GROUP S.r.l. - Società Unipersonale Via Lombardia, 2 37044 Cologna Veneta (VR) Italy
Testing Laboratory	LabAnalysis S.r.l. Via Europa 5, 27041 Casanova Lonati (PV) Italy
Sample Submitted:	Air Sanitizer "MAIA" (batch N° MAC1S 2012 5908)
LabAnalysis code:	FD-21-000035-000058
Report Editing by:	Fabio De Leonardis RALTBCF1
Verified by:	Guido Premoli DTAM

LabAnalysis
HIGH QUALITY CONTROLS

1. SUMMARY

The virucidal activity of the product was assessed exposing a surface pre-treated with a viral test suspension to the test item, at the conditions defined by the customer and described below. After the prescribed incubation time, the viral suspension was inoculated in the appropriate cellular monolayer. At the end of the incubation period, cellular cultures were observed by microscopy for the detection of cytopathic effects (CPE) produced by viral multiplication.
The verification of the methodology was performed in compliance to the reference method.
All detailed results for each test performed are reported in the chapter 2.

1.1 PRODUCT IDENTIFICATION

This study was conducted on the test item Air Sanitizer "MAIA", a static unit with bipolar ionization technology. See Table 1 for sample identification:

Table 1: Sample identification

Test item	Active Ingredient	Storage conditions	Batch	Production date	Expiry date	LabAnalysis internal code
Air Sanitizer "MAIA"	negative oxygen ions	n.a.	MAC1S 2012 5908	12/2020	n.d.	FD-21-000035-000058

1.2 ASSAY SYSTEM

In order to evaluate the virucidal effectiveness the product was tested against the virus model inoculated in sensitive host cell line. See Table 2 for the biological system used for the tests of the study:

Table 2: Biological Assay System

Virus type	Host Cell Line
Vaccinia virus, strain Elstree, ATCC VR-1549	Vero cells, ATCC CCL-81

1.3 EXPERIMENTAL CONDITION

The test item was analysed at the following conditions summarized in Table 3:

Table 3: Virucidal Activity Assay Condition

Contact Temperature	20 ± 1 °C
Contact Time	15 / 30 / 45 / 60 minutes
Interfering Substance	0.3 g/L BSA (Clean conditions)
Sample concentrations	Saturated air condition by negative oxygen ions

1.3.1 METHOD OF SUPPRESSION (FOR REFERENCE TEST)

To suppress the virucidal activity, the mixtures of interfering substance, Reference material and virus suspension recovered with ice-cold medium from inoculated surface, were kept in ice bath during the serial dilutions preparation.

1.4 PERIOD OF ANALYSIS

Tests started on: 11/01/2021
Tests completed on: 15/02/2021

2. RESULTS

All the raw data recorded for each test of this study are reported in validated data sheet used to perform the computation of the required parameters following the Spearman-Karber method.

2.1 VALIDATION OF THE ASSAY FOR VIRUCIDAL ACTIVITY

The results obtained to verify assay validity are reported in the Table 4 below. Due to the type of product under examination, some of the test recommended in the EN 16777 are not applicable.

Table 4: Assay Validation Results - Vaccinia virus, strain Elstree

Assay Performed	Results (with 95% confidence interval)	Assay Validity
Sample cytotoxicity	CPE < 1 (< 25 % of cell monolayer destruction)	Not Applied
Virus stock solution titration	Virus Titre (-log $TCID_{50}$/mL) = 7.33 ± 0.34	VALID
Cell susceptibility to virus	Not Applied	Not Applied
Suppression of virucidal activity	Not Applied	Not Applied
Reference test for virus inactivation	$TCID_{50}$ reduction after 5 min: 1.00 ± 0.63	VALID

The assay validity criteria for all the performed controls were satisfied.

2.2 VIRUCIDAL ACTIVITY ASSAY

The results obtained for the reduction of virus infectivity expressed as logarithm values, at the different incubation time points and conditions applied in the test are reported table 5.

Table 5: Results - Vaccinia virus, strain Elstree

Product Code/Name	Experimental Conditions		Control / Sample Virus Titre (-log TCID50/mL) with 95% confidence interval after contact time	Reduction with 95% confidence interval
	Incubation Time point (min)	Interfering Substance		
FD-21-000035-000058 "MAIA"	15	0.3 g/L BSA (Clean)	6.83 ± 0.56 / 6.33 ± 0.34	0.50 ± 0.65
FD-21-000035-000058 "MAIA"	30	0.3 g/L BSA (Clean)	7.00 ± 0.45 / 5.33 ± 0.34	1.67 ± 0.56
FD-21-000035-000058 "MAIA"	45	0.3 g/L BSA (Clean)	7.17 ± 0.42 / 4.17 ± 0.42	3.00 ± 0.59
FD-21-000035-000058 "MAIA"	60	0.3 g/L BSA (Clean)	7.50 ± 0.00 / 3.50 ± 0.00	4.00 ± 0.00

2.3 INTERPRETATION OF RESULTS

In agreement to the UNI EN 16777:2019 the product shall demonstrate a titre reduction of 4 log or more compared to the virus control titration ("PASS"), not considering the 95% confidential interval.
Therefore, the results obtained in the present study can be summarized in the following Table 6:

Table 6: Assay Outcome

Product Code/Name	Experimental Conditions		Reduction with 95% confidence interval	Assay Outcome
	Incubation Time point (min)	Virus model		
FD-21-000035-000058 "MAIA"	15	Vaccinia virus, strain Elstree	0.50 ± 0.65	NOT PASS
FD-21-000035-000058 "MAIA"	30	Vaccinia virus, strain Elstree	1.67 ± 0.56	NOT PASS
FD-21-000035-000058 "MAIA"	45	Vaccinia virus, strain Elstree	3.00 ± 0.59	NOT PASS
FD-21-000035-000058 "MAIA"	60	Vaccinia virus, strain Elstree	4.00 ± 0.00	**PASS**

3. CONCLUSION

On the basis of the obtained results, operating following the indications of the UNI EN 16777, the device Air Sanitizer "MAIA" tested in clean conditions, at 20 °C **proves virucidal activity** against Vaccinia virus, after exposure of 60 minutes.

Therefore, the product can be considered effective against all enveloped viruses (including the coronaviruses such as SARS-Cov-2), as defined in the Annex A of the standard EN 16777:2019.

LabAnalysis
HIGH QUALITY CONTROLS

Annex A
(informative)

Examples of viruses sorted according to their presence in the human body in case of virus infection

These viruses may contaminate hands, instruments, other surfaces and textiles.

NOTE 1 This list is not exhaustive.

NOTE 2 Enveloped viruses are in bold

Blood	
Enterovirus	**Hepatitis C virus (HCV)**
Filoviridae	**Hepatitis Delta virus (HDV)**
Flavivirus	**Human Immunodeficiency Virus (HIV)**
Herpesviridae	**Human T-Cell Leukaemia Virus (HTLV)**
Hepatitis A Virus (HAV)	Parvovirus B 19
Hepatitis B virus (HBV)	
Respiratory tract	
Adenovirus (Mast-)	**Influenza Virus**
Coronavirus	**Paramyxoviridae**
Enterovirus	Rhinovirus
Herpesviridae	**Rubella Virus**
Neuronal tissue, ear and nose, eye	
Adenovirus (Mast-)	**Human Immunodeficiency Virus (HIV)**
Enterovirus	Polyomavirus
Herpesviridae	**Rabies Virus**
Measles Virus	**Rubella Virus**
Gastro-intestinal	
Adenovirus(Mast-)	Enterovirus
Caliciviridae	Hepatitis A Virus (HAV)
Coronavirus	Hepatitis E Virus (HEV)
Astrovirus	Rotavirus
Skin, breast and/or milk	
Enterovirus	**Human T-Cell Leukaemia Virus (HTLV)**
Herpesviridae	Papillomavirus
Human Immunodeficiency Virus (HIV)	**Poxviridae**

LabAnalysis
HIGH QUALITY CONTROLS

Spleen and lymph nodes (see also „Blood")

Human T-Cell Leukaemia Virus (HTLV)

Human Immunodeficiency Virus (HIV)

Dental procedure

Adenovirus(Mast-)

Enterovirus

Herpesviridae

Hepatitis B virus (HBV)

Hepatitis C Virus (HCV)

Hepatitis Delta Virus (HDV)

Human Immunodeficiency Virus (HIV)

Urogenital tract

Hepatitis B Virus (HBV)

Herpesviridae

Human Immunodeficiency Virus (HIV)

Human T-Cell Leukaemia Virus (HTLV)

Papillomavirus

Polyomavirus

Reference:

Van Regenmortel MHV et al.,Eds.: Virus Taxonomy, Classification and Nomenclature of Viruses, seventh report of the international committee on taxonomy of viruses.

Academic Press, San Diego, 2000

LabAnalysis
HIGH QUALITY CONTROLS

TECHNICAL REPORT

VIRUCIDAL ACTIVITY STUDY OF THE "MAIA" PRODUCT (UNI EN 16777:2019)

Technical Report N° D202101670

Customer:	SKILL GROUP S.r.l. - Società Unipersonale Via Lombardia, 2 37044 Cologna Veneta (VR) Italy
Testing Laboratory	LabAnalysis S.r.l. Via Europa 5, 27041 Casanova Lonati (PV) Italy
Sample Submitted:	Air Sanitizer "MAIA" (batch N° MAC1S 2012 5908)
LabAnalysis code:	FD-21-000035-000058
Report Editing by:	Fabio De Leonardis RALTBCF1
Verified by:	Guido Premoli DTAM

LabAnalysis
HIGH QUALITY CONTROLS

1. SUMMARY

The virucidal activity of the product was assessed exposing a surface pre-treated with a viral test suspension to the test item, at the conditions defined by the customer and described below. After the prescribed incubation time, the viral suspension was inoculated in the appropriate cellular monolayer. At the end of the incubation period, cellular cultures were observed by microscopy for the detection of cytopathic effects (CPE) produced by viral multiplication.
The verification of the methodology was performed in compliance to the reference method.
All detailed results for each test performed are reported in the chapter 2.

1.1 PRODUCT IDENTIFICATION

This study was conducted on the test item Air Sanitizer "MAIA", a static unit with bipolar ionization technology. See Table 1 for sample identification:

Table 1: Sample identification

Test item	Active Ingredient	Storage conditions	Batch	Production date	Expiry date	LabAnalysis internal code
Air Sanitizer "MAIA"	negative oxygen ions	n.a.	MAC1S 2012 5908	12/2020	n.d.	FD-21-000035-000058

1.2 ASSAY SYSTEM

In order to evaluate the virucidal effectiveness the product was tested against the virus model inoculated in sensitive host cell line. See Table 2 for the biological system used for the tests of the study:

Table 2: Biological Assay System

Virus type	Host Cell Line
Adenovirus type 5, strain Adenoid 75, ATCC-VR-5	HeLa ATCC CCL-2

1.3 EXPERIMENTAL CONDITION

The test item was analysed at the following conditions summarized in Table 3:

Table 3: Virucidal Activity Assay Condition

Contact Temperature	20 ± 1 °C
Contact Time	15 / 30 / 45 minutes
Interfering Substance	0.3 g/L BSA (Clean conditions)
Sample concentrations	Saturated air condition by negative oxygen ions

1.3.1 METHOD OF SUPPRESSION (FOR REFERENCE TEST)

To suppress the virucidal activity, the mixtures of interfering substance, Reference material and virus suspension recovered with ice-cold medium from inoculated surface, were kept in ice bath during the serial dilutions preparation.

1.4 PERIOD OF ANALYSIS

Tests started on: 11/01/2021
Tests completed on: 15/02/2021

2. RESULTS

All the raw data recorded for each test of this study are reported in validated data sheet used to perform the computation of the required parameters following the Spearman-Karber method.

2.1 VALIDATION OF THE ASSAY FOR VIRUCIDAL ACTIVITY

The results obtained to verify assay validity are reported in Table 4. Due to the type of product under examination, some of the test recommended in the EN 16777 are not applicable.

Table 4: Assay Validation Results - Adenovirus type 5, strain Adenoid 75

Assay Performed	Results (with 95% confidence interval)	Assay Validity
Sample cytotoxicity	Not Applied	Not Applied
Virus stock solution titration	Virus Titre (-log $TCID_{50}$/mL) = 7.83 ± 0.42	VALID
Cell susceptibility to virus	Not Applied	Not Applied
Suppression of virucidal activity	Not Applied	Not Applied
Reference test for virus inactivation	$TCID_{50}$ reduction after 5 min: 3.17 ± 0.34	VALID

The assay validity criteria for all the performed controls were satisfied.

2.2 VIRUCIDAL ACTIVITY ASSAY

The results obtained for the reduction of virus infectivity expressed as logarithm values, at the different incubation time points and conditions applied in the test are reported in Table 5.

Table 5: Results - Adenovirus type 5, strain Adenoid 75

Product Code/Name	Experimental Conditions		Control / Sample Virus Titre (-log TCID50/mL) with 95% confidence interval after contact time	Reduction with 95% confidence interval
	Incubation Time point (min)	Interfering Substance		
FD-21-000035-000058 "MAIA"	15	0.3 g/L BSA (Clean)	7.00 ± 0.45 / 4.00 ± 0.45	3.00 ± 0.63
FD-21-000035-000058 "MAIA"	30	0.3 g/L BSA (Clean)	7.50 ± 0.00 / 3.50 ± 0.00	4.00 ± 0.00

LabAnalysis
HIGH QUALITY CONTROLS

Product Code/Name	Experimental Conditions		Control / Sample Virus Titre (-log TCID50/mL) with 95% confidence interval after contact time	Reduction with 95% confidence interval
	Incubation Time point (min)	Interfering Substance		
FD-21-000035-000058 "MAIA"	45	0.3 g/L BSA (Clean)	7.67 ± 0.34 / 3.50 ± 0.00	4.17 ± 0.34

2.3 INTERPRETATION OF RESULTS

In agreement to the UNI EN 16777:2019 the product shall demonstrate a titre reduction of 4 log or more compared to the virus control titration ("PASS"), not considering the 95% confidential interval.
Therefore, the results obtained in the present study for the reliable time point, can be summarized in the following Table 6:

Table 6: Assay Outcome

Product Code/Name	Experimental Conditions		Reduction with 95% confidence interval	Assay Outcome
	Incubation Time point (min)	Virus model		
FD-21-000035-000058 "MAIA"	15	Adenovirus type 5, strain Adenoid 75	3.00 ± 0.63	NOT PASS
FD-21-000035-000058 "MAIA"	30	Adenovirus type 5, strain Adenoid 75	4.00 ± 0.00	**PASS**
FD-21-000035-000058 "MAIA"	45	Adenovirus type 5, strain Adenoid 75	4.17 ± 0.34	**PASS**

3. CONCLUSION

On the basis of the obtained results, operating following the indications of the UNI EN 16777, the device Air Sanitizer "MAIA" tested in clean conditions, at 20 °C **proves virucidal activity** against the Adenovirus after incubation of 30 and 45 minutes.

Bioxigen®

your best indoor air quality

Skill Group S.r.l.
Via Lombardia, 2 - Cologna Veneta (VR) 37044 - ITALY
Tel +39 (0)41 5931151 | Fax +39 (0)41 5931158
www.bioxigen.com | sales@bioxigen.com

Distributore Autorizzato / Dealer

BXTC-19 03-2021-EN Boz

DISTRIBUTOR IN VIETNAM:
BACH KHOA INTERNATIONAL EQUIPMENT JSC

bkic.vn | info@bkic.vn | +84 903 999 357