TEST REPORT

SOP and results with (#) are not included in the ENAC acreditation scope

Job No./Report No: 21-006111
Date: **28/05/2021**

Client: ISPT Ugarte, SL **Code:** CL-1648
Address: San Andres Auzoa,2-6 ARRASATE/MONDRAGÓN GUIPUZKOA ESPAÑA
Attn: Arantzazu Ugarte **e-MAIL:** orlegia@orlegia.com
Tel: 0034 627831505 **Fax:**

The following sample was (were) submitted and identified by the client as:

		Job no Report No.:	**21-006111**
Serie :		Receiving Date:	**13/05/2021**
Batch No.:		Test Start Date:	**28/05/2021**
Reference No.:	**MASCARILLA TRANSPARENTE BLANCA**	Test End Date:	**28/05/2021**
Composition indicated:	**unknown**	Sample description:	**HIGIENICAL MASKS**

#SUMMARY OF TEST CONCLUSIONS

SOP description	#Conclusions
#SOP305 - Method of washing, cleaning and disinfection (Masks and Fabrics for masks)	Pass
#SOP 342- Bacterial Filtration Efficiency (BFE) - (Test subcontracted to an accredited laboratory)	Pass
#SOP 342- Bacterial Filtration Efficiency (BFE)-After Washing (Test subcontracted to an accredited lab)	Pass
#SOP347 - Determination of breathability (Differential Pressure) by UNE-EN 14683 annex C - Original	Pass
#SOP347 - Determination of breathability (Differential Pressure) by UNE-EN 14683 annex C - After Washing	Pass
SOP106 - Determination of Air Permeability by ISO 9237 (for CWA 17553) - Original	Pass
SOP106 - Determination of Air Permeability by ISO 9237 (for CWA 17553) - After washing	Pass

Sample Tested

-The laboratory is not responsible for the information received by the client (grey shaded fields)
-Reported results do not include uncertainties (but are available for the customer).
-Opinions and interpretations expressed herein are outside the scope of accreditation.
-Unless otherwise stated the result shown in this test report refer only the sample/s tested and such sample/s are retained for 30 days only.
-Test reports without AMSLab seal and authorized signatures are invalid.
-This document can't be reproduced or modified except in full, without prior given approval of the company.
-Any printed copy of this document is copy from the original digital document.

Job No./Report No: 21-006111
Date: **28/05/2021**

SOP and results with (#) are not included in the ENAC acreditation scope

SOP305 - Method of washing, cleaning and disinfection (Masks and Fabrics for masks)

ID	ID AMSLab	Description	# Conclusion
3	S-210513-00217	MASK TRANSPARENT (ORIGINAL)	Pass

	CAS	S-210513-00217
Change of appearance after washing		Slight change
Number of cycles		30
Washing Temperature		60ºC
Method		1

Notes:
Note 1: Internal method SOP/305 rev. 1: Washing and drying process applied based on Document from the Ministry of Health published on April 15, 2020 "Cleaning and disinfection of reusable hygienic masks"

Note 2, Washing Applied method:
- Method 1: Washing with normal detergent and water at a temperature of 60º (Normal cycle by washing machine)
- Method 2: 1:50 dilution of bleach with water for 30 minutes.
- Method 3.1: By washing machine with virucidal disinfectant (Sanytol)
- Method 3.2: By hand with virucidal disinfectant (Sanytol)

Note 3:
Drying procedure used: Method A: in air

- n.a.: not applicable

Note 4 (Only for methods 1 and 3.1):
- Detergent used: Reference 3
- Type of counterweight used: Type III (100% polyester) / Type II (50%cotton 50%polyester) / Type I (100% cotton)

Note 5 - Meaning of the grades of change of appearance:
- No change: without changes
- Slight change: there is a slight change in appearance or color.
- Moderate change: there is a moderate change in appearance or apparent defects.
- Severe change: there is a severe change in appearance or apparent serious defects.

Requierement: No change and Slight change will be considered acceptable appearance change. Moderate change and Severe change will be considered unacceptable appearance change.

Notes of change of appearance (If applicable):

SOP 342- Bacterial Filtration Efficiency (BFE) - (Test subcontracted to an accredited laboratory)

ID	ID AMSLab	Description	# Conclusion
6	S-210513-00220	MASK TRANSPARENT (ORIGINAL)	Pass

Applied Mass Spectrometry Laboratory, S.L.U.Avda. Benigno Rivera, nº56 27003 Lugo (Spain)
Tel.: +34 982808074 - Fax.: +34 982803180 analysis@ams-lab.com / www.ams-lab.com

SOP and results with (#) are not included
in the ENAC acreditation scope

Job No./Report No: 21-006111
Date: **28/05/2021**

	CAS	S-210513-00220
Test 1: Bacterial Filtration Efficiency		95.4
Test 1: Number of Bacteria		138
Test 2: Bacterial Filtration Efficiency		95.3
Test 2: Number of Bacteria		141
Test 3: Bacterial Filtration Efficiency		95.1
Test 3: Number of Bacteria		146
Test 4: Bacterial Filtration Efficiency		95.1
Test 4: Number of Bacteria		148
Test 5: Bacterial Filtration Efficiency		95.2
Test 5: Number of Bacteria		145

Test Method: EN 14683:2019+AC:2019 (TS EN 14683+AC:2019) Annex-B / Medical Face Masks - Requirements and Test Methods

Requirements by specifications:
Spanish specification UNE 0064:2020: >=95%
Spanish specification UNE 0065:2020: >= 90%
European specification CWA 17553:2020: Level >= 90% and
European specification CWA 17553:2020: Level >= 70%

Other requirements:
- Surgical Mask type I by UNE-EN 14683: >= 95%
- Surgical Mask type II by UNE-EN 14683: >= 98%
- Surgical Mask type IIR by UNE-EN 14683: >= 98%

Report unit Bacterial Filtration Efficiency = %
Report unit Number of Bacteria = cfu/mL
A specimen of the mask material is clamped between a impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency 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.

Test Flow Rate: 28,3 L/min
Test Flow Time: 2 minute
Sample Sizes: 10x10 cm2
Microorganism: Staphylococcus aureus ATCC 6538
Bacterial concentration (cfu/ml): 5x10E5 cfu/ml
Incubation conditions: 24 hour, 35C ± 2C
Positive control sample average of number of Bacteria (C): 3.0x10E3 cfu/ml

(*) Test subcontracted and accredited laboratory (EKOTEKS LABORATUVAR VE GÖZETM HZMETLER A. .) for medical mask for tests (EN 14683). Results in subcontracted report number: 21015908
The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.
EKOTEKS LABORATUVAR VE GÖZETM HZMETLER A. . Deney Laboratuvar, is accredited by TURKAK under registration number (AB-0583-T) for ISO 17025:2017 as test laboratory.

Job No./Report No: 21-006111
Date: **28/05/2021**

SOP and results with (#) are not included in the ENAC acreditation scope

SOP 342- Bacterial Filtration Efficiency (BFE)-After Washing (Test subcontracted to an accredited lab)

ID	ID AMSLab	Description	# Conclusion
7	S-210513-00221	MASK TRANSPARENT (AFTER 30 WASHING CYCLES AT 60ºC)	Pass

	CAS	S-210513-00221
Test 1: Bacterial Filtration Efficiency		90.7
Test 1: Number of Bacteria		279
Test 2: Bacterial Filtration Efficiency		90.9
Test 2: Number of Bacteria		274
Test 3: Bacterial Filtration Efficiency		90.8
Test 3: Number of Bacteria		275
Test 4: Bacterial Filtration Efficiency		90.5
Test 4: Number of Bacteria		284
Test 5: Bacterial Filtration Efficiency		90.6
Test 5: Number of Bacteria		283

Test Method: EN 14683:2019+AC:2019 (TS EN 14683+AC:2019) Annex-B / Medical Face Masks - Requirements and Test Methods

Requirements by specifications:
Spanish specification UNE 0064:2020: >=95%
Spanish specification UNE 0065:2020: >= 90%
European specification CWA 17553:2020: Level >= 90% and
European specification CWA 17553:2020: Level >= 70%

Other requirements:
- Surgical Mask type I by UNE-EN 14683: >= 95%
- Surgical Mask type II by UNE-EN 14683: >= 98%
- Surgical Mask type IIR by UNE-EN 14683: >= 98%

Report unit Bacterial Filtration Efficiency = %
Report unit Number of Bacteria = cfu/mL
A specimen of the mask material is clamped between a impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency 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.

Test Flow Rate: 28,3 L/min
Test Flow Time: 2 minute
Sample Sizes: 10x10 cm2
Microorganism: Staphylococcus aureus ATCC 6538
Bacterial concentration (cfu/ml): 5x10E5 cfu/ml
Incubation conditions: 24 hour, 35C ± 2C
Positive control sample average of number of Bacteria (C): 3.0x10E3 cfu/ml

(*) Test subcontracted and accredited laboratory (EKOTEKS LABORATUVAR VE GÖZETM HZMETLER A. .) for medical mask for tests (EN 14683). Results in subcontracted report number: 21015909
The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.
EKOTEKS LABORATUVAR VE GÖZETM HZMETLER A. . Deney Laboratuvar, is accredited by TURKAK under registration number (AB-0583-T) for ISO 17025:2017 as test laboratory.

Job No./Report No: 21-006111
Date: **28/05/2021**

SOP and results with (#) are not included in the ENAC acreditation scope

SOP347 - Determination of breathability (Differential Pressure) by UNE-EN 14683 annex C - Original

ID	ID AMSLab	Description	# Conclusion
1	S-210513-00215	MASK TRANSPARENT (ORIGINAL)	Pass

BREATHABILITY RESULTS (DIFFERENTIAL PRESSURE)

TEST PIECE	A1 (Pa)	A2 (Pa)	A3 (Pa)	A4 (Pa)	A5 (Pa)	AVERAGE VALUE (Pa)	ΔP (Pa/cm2)
1	2	2	2	2	3	2.3	0.5
2	4	4	4	3	3	3.4	0.7
3	2	2	2	2	2	2.0	0.4
4	3	2	2	3	3	2.5	0.5
5	3	3	3	3	3	3.1	0.6
					AVERAGE		0.5
					STANDARD DEVIATION (25 VALUES)		0.6

Notes:
Note 1: Applied standard UNE-EN 14683:2019+AC:2019 Annex C for breathability (Differential Pressure)
Note 2: For requirements: Spanish Specification UNE 0064-1, 0064-2, 0065 and European Specification CWA 17553
Note 3: Size of test specimen: 4.9 cm2
Note 4: Tested area of the test specimen: 2.5 cm
Note 5: Flow of air: (8 ± 0.2) l/min
Note 6: Report Unit: Pa and P (Pa/cm2)
Note 7: Number of samples tested: 5 / Number of measurements: 5
Note 8: Conditioned samples: 4 hours at (21 ± 5) ºC and (85 ± 5) %HR
Note 9: A: sample area tested
Note 10: n.a. = not applicable

Requirements by specifications:
- Non-reusable Hygienic Mask by UNE 0064-1-2: < 60 Pa/cm2
- Reusable Hygienic Mask by UNE 0065: < 60 Pa/cm2
- European specification CWA 17553:2020: <= 70 Pa/cm2

Other requirements:
- Surgical Mask type I by UNE-EN 14683: < 40 Pa/cm2
- Surgical Mask type II by UNE-EN 14683: < 40 Pa/cm2
- Surgical Mask type IIR by UNE-EN 14683: < 60 Pa/cm2

Specific Notes:
(**) The result is out of specifications

Applied Mass Spectrometry Laboratory, S.L.U.Avda. Benigno Rivera, n°56 27003 Lugo (Spain)
Tel.: +34 982808074 - Fax.: +34 982803180 analysis@ams-lab.com / www.ams-lab.com

SOP and results with (#) are not included in the ENAC acreditation scope

Job No./Report No: 21-006111
Date: **28/05/2021**

SOP347 - Determination of breathability (Differential Pressure) by UNE-EN 14683 annex C - After Washing

ID	ID AMSLab	Description	# Conclusion
2	S-210513-00216	MASK TRANSPARENT (AFTER 30 WASHING CYCLES AT 60ºC)	Pass

BREATHABILITY RESULTS (DIFFERENTIAL PRESSURE)							
TEST PIECE	**A1 (Pa)**	**A2 (Pa)**	**A3 (Pa)**	**A4 (Pa)**	**A5 (Pa)**	**AVERAGE VALUE (Pa)**	ΔP (Pa/cm2)
1	8	8	7	8	8	7.8	1.6
2	9	9	10	9	10	9.5	1.9
3	7	7	8	7	7	7.3	1.5
4	9	10	9	10	11	9.8	2.0
5	12	11	11	11	12	11.2	2.3
					AVERAGE		1.9
					STANDARD DEVIATION (25 VALUES)		1.5

Notes:
Note 1: Applied standard UNE-EN 14683:2019+AC:2019 Annex C for breathability (Differential Pressure)
Note 2: For requirements: Spanish Specification UNE 0064-1, 0064-2, 0065 and European Specification CWA 17553
Note 3: Size of test specimen: 4.9 cm2
Note 4: Tested area of the test specimen: 2.5 cm
Note 5: Flow of air: (8 ± 0.2) l/min
Note 6: Report Unit: Pa and P (Pa/cm2)
Note 7: Number of samples tested: 5 / Number of measurements: 5
Note 8: Conditioned samples: 4 hours at (21 ± 5) ºC and (85 ± 5) %HR
Note 9: A: sample area tested
Note 10: n.a. = not applicable

Requirements by specifications:
- Non-reusable Hygienic Mask by UNE 0064-1-2: < 60 Pa/cm2
- Reusable Hygienic Mask by UNE 0065: < 60 Pa/cm2
- European specification CWA 17553:2020: <= 70 Pa/cm2

Other requirements:
- Surgical Mask type I by UNE-EN 14683: < 40 Pa/cm2
- Surgical Mask type II by UNE-EN 14683: < 40 Pa/cm2
- Surgical Mask type IIR by UNE-EN 14683: < 60 Pa/cm2

Specific Notes:
(**) The result is out of specifications

Applied Mass Spectrometry Laboratory, S.L.U.Avda. Benigno Rivera, nº56 27003 Lugo (Spain)
Tel.: +34 982808074 - Fax.: +34 982803180 analysis@ams-lab.com / www.ams-lab.com

Job No./Report No: 21-006111
Date: **28/05/2021**

SOP and results with (#) are not included in the ENAC acreditation scope

SOP106 - Determination of Air Permeability by ISO 9237 (for CWA 17553) - Original

ID	ID AMSLab	Description	# Conclusion
4	S-210513-00218	MASK TRANSPARENT (ORIGNIAL)	Pass

	CAS	S-210513-00218
(I.C. 95%) - Confidence Interval ±		0.0
Mean Value air permeability (l/m2/seg)		>1000.0
Standard deviation		0.0
Value 10 (l/m2/seg)		>1000.0
Value 1 (l/m2/seg)		>1000.0
Value 2 (l/m2/seg)		>1000.0
Value 3 (l/m2/seg)		>1000.0
Value 4 (l/m2/seg)		>1000.0
Value 5 (l/m2/seg)		>1000.0
Value 6 (l/m2/seg)		>1000.0
Value 7 (l/m2/seg)		>1000.0
Value 8 (l/m2/seg)		>1000.0
Value 9 (l/m2/seg)		>1000.0

Notes:
Note 1: Applied standard UNE-EN ISO 9237:1996 (equivalent to ISO 9237:1995)
Note 2: Applied pressure: 100 Pa
Note 3: Applied area: 5 cm2
Note 4: Report Unit: l/m2/seg (= mm/seg)
Note 5: Number of measurements: 10
Note 6: Conditioned samples: 24 hours at 20 ± 2 ºC and 65 ± 4 HR
Note 7: n.a. = not applicable
Note 8: Standard deviation units and I.C. 95% units: l/m2/seg

Requirements by specifications:
(#: The standards listed below are not included in the ENAC accreditation scope, they are only indicated to inform the applicable requirement)
- European specification CWA 17553:2020: >= 96 l/m2/s

Specific Notes:
(**) The result is out of specifications

SOP106 - Determination of Air Permeability by ISO 9237 (for CWA 17553) - After washing

ID	ID AMSLab	Description	# Conclusion
5	S-210513-00219	MASK TRANSPARENT (AFTER 30 WASHING CYCLES AT 60ºC)	Pass

	CAS	S-210513-00219
(I.C. 95%) - Confidence Interval ±		0.0
Mean Value air permeability (l/m2/seg)		>1000.0
Standard deviation		0.0
Value 10 (l/m2/seg)		>1000.0
Value 1 (l/m2/seg)		>1000.0

Applied Mass Spectrometry Laboratory, S.L.U.Avda. Benigno Rivera, n°56 27003 Lugo (Spain)
Tel.: +34 982808074 - Fax.: +34 982803180 analysis@ams-lab.com / www.ams-lab.com

SOP and results with (#) are not included in the ENAC acreditation scope

Job No./Report No: 21-006111

Date: **28/05/2021**

	CAS	S-210513-00219
Value 2 (l/m2/seg)		>1000.0
Value 3 (l/m2/seg)		>1000.0
Value 4 (l/m2/seg)		>1000.0
Value 5 (l/m2/seg)		>1000.0
Value 6 (l/m2/seg)		>1000.0
Value 7 (l/m2/seg)		>1000.0
Value 8 (l/m2/seg)		>1000.0
Value 9 (l/m2/seg)		>1000.0

Notes:
Note 1: Applied standard UNE-EN ISO 9237:1996 (equivalent to ISO 9237:1995)
Note 2: Applied pressure: 100 Pa
Note 3: Applied area: 5 cm2
Note 4: Report Unit: l/m2/seg (= mm/seg)
Note 5: Number of measurements: 10
Note 6: Conditioned samples: 24 hours at 20 ± 2 ºC and 65 ± 4 HR
Note 7: n.a. = not applicable
Note 8: Standard deviation units and I.C. 95% units: l/m2/seg

Requirements by specifications:
(#: The standards listed below are not included in the ENAC accreditation scope, they are only indicated to inform the applicable requirement)
- European specification CWA 17553:2020: >= 96 l/m2/s

Specific Notes:
(**) The result is out of specifications

Issue Date: 28/05/2021

Signed: Manuel Lolo — General Manager

Signed: Pablo Perez — Chemical Lab Manager

Signed: Esteban Ramirez — Physical Lab Manager

Test report reviewed by Esteban Ramírez (Physical Tests) and Pablo Pérez (Chemical Tests)

Applied Mass Spectrometry Laboratory, S.L.U.Avda. Benigno Rivera, n°56 27003 Lugo (Spain)
Tel.: +34 982808074 - Fax.: +34 982803180 analysis@ams-lab.com / www.ams-lab.com