

Job No./Report No: 21-002396

Date: 29/03/2021

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

SOP305 - Change of appearance after washing (Garments and fabrics)

ID	ID AMSLab	Description	# Conclusion
8	S-210226-00192	MASK BLACK (AFTER 5 WASHING CYCLES AT 60°C)	Pass
9	S-210226-00193	MASK BLACK (AFTER 20 WASHING CYCLES AT 60°C)	Pass
10	S-210226-00194	MASK BLACK (AFTER 30 WASHING CYCLES AT 60°C)	Pass
11	S-210226-00195	MASK BLACK (AFTER 40 WASHING CYCLES AT 60°C)	Pass
12	S-210226-00196	MASK BLACK (AFTER 50 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210226-00192	S-210226-00193	S-210226-00194	S-210226-00195
Change of appearance after washing		No change	No change	Slight change	Slight change
Number of cycles		5	20	30	40
Washing Temperature		60°C	60°C	60°C	60°C

	CAS	S-210226-00196
Change of appearance after washing		Slight change
Number of cycles		50
Washing Temperature		60°C

Notes:

Note 1: Washing and drying process applied based on UNE-EN ISO 6330:2012

Note 2:

- Detergent: 20 gr of Commercial detergent / - Drying procedure: Air dry without tumble dry.
- n.a.: not applicable
- Requirement: No obvious change or slight change/colour/shape/appearance/seams/embroidery/trimmings/applications

Note 3 - Meaning of the grades of change of appearance:

- No change in appearance after washing and drying process
- Slight change in appearance after washing and drying process
- Moderate change in appearance after washing and drying process
- Severe change in appearance after washing and drying process

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

ID	ID AMSLab	Description	# Conclusion
2	S-210226-00186	MASK BLACK (ORIGINAL)	Pass

	CAS	S-210226-00186
Test 1: Bacterial Filtration Efficiency		95.2
Test 1: Number of Bacteria		144
Test 2: Bacterial Filtration Efficiency		95.6
Test 2: Number of Bacteria		133
Test 3: Bacterial Filtration Efficiency		95.3
Test 3: Number of Bacteria		142
Test 4: Bacterial Filtration Efficiency		95.2
Test 4: Number of Bacteria		145
Test 5: Bacterial Filtration Efficiency		95.0
Test 5: Number of Bacteria		149

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: $\geq 95\%$

Spanish specification UNE 0065:2020: $\geq 90\%$

European specification CWA 17553:2020: Level $\geq 90\%$ and

European specification CWA 17553:2020: Level $\geq 70\%$

Other requirements:

- Surgical Mask type I by UNE-EN 14683: $\geq 95\%$

- Surgical Mask type II by UNE-EN 14683: $\geq 98\%$

- Surgical Mask type IIR by UNE-EN 14683: $\geq 98\%$

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 \pm 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: 21008610

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. . Denedy Laboratuvar, is accredited by TURKAK under registration number (AB-0583-T) for ISO 17025:2017 as test laboratory.

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

ID	ID AMSLab	Description	# Conclusion
13	S-210226-00197	MASK BLACK (AFTER 5 WASHING CYCLES AT 60°C)	Pass
14	S-210226-00198	MASK BLACK (AFTER 20 WASHING CYCLES AT 60°C)	See Results
15	S-210226-00199	MASK BLACK (AFTER 30 WASHING CYCLES AT 60°C)	See Results
16	S-210226-00200	MASK BLACK (AFTER 40 WASHING CYCLES AT 60°C)	See Results
17	S-210226-00201	MASK BLACK (AFTER 50 WASHING CYCLES AT 60°C)	See Results

	CAS	S-210226-00197	S-210226-00198	S-210226-00199	S-210226-00200
Test 1: Bacterial Filtration Efficiency		92.3	88.1	86.3	84.7
Test 1: Number of Bacteria		231	358	411	459
Test 2: Bacterial Filtration Efficiency		92.4	88.3	86.5	84.6
Test 2: Number of Bacteria		228	350	405	461
Test 3: Bacterial Filtration Efficiency		92.1	88.4	86.4	84.7
Test 3: Number of Bacteria		236	347	409	459
Test 4: Bacterial Filtration Efficiency		92.1	88.5	86.2	84.4
Test 4: Number of Bacteria		238	346	415	469
Test 5: Bacterial Filtration Efficiency		92.1	88.7	86.0	84.8
Test 5: Number of Bacteria		238	338	419	455

	CAS	S-210226-00201
Test 1: Bacterial Filtration Efficiency		82.9
Test 1: Number of Bacteria		513
Test 2: Bacterial Filtration Efficiency		82.8
Test 2: Number of Bacteria		515
Test 3: Bacterial Filtration Efficiency		82.6
Test 3: Number of Bacteria		522
Test 4: Bacterial Filtration Efficiency		82.4
Test 4: Number of Bacteria		529
Test 5: Bacterial Filtration Efficiency		82.8
Test 5: Number of Bacteria		515

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:

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- 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: 21008611 for samples for 5 washing cycles, 21008612 for samples for 20 washing cycles, 21008613 for samples for 30 washing cycles, 21008614 for samples for 40 washing cycles and 21008615 for samples for 50 washing cycles. 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.

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T) for ISO 17025:2017 as test laboratory.

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

ID	ID AMSLab	Description	# Conclusion
1	S-210226-00185	MASK BLACK (ORIGINAL)	Pass

	CAS	S-210226-00185
Average Differential pressure (Pa/cm ²)		<1
Value 1 Differential pressure (Pa/cm ²)		<1
Value 2 Differential pressure (Pa/cm ²)		<1
Value 3 Differential pressure (Pa/cm ²)		<1
Value 4 Differential pressure (Pa/cm ²)		<1
Value 5 Differential pressure (Pa/cm ²)		<1

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 °C and 85 ± 5 HR

Note 9: 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

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- 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

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

ID	ID AMSLab	Description	# Conclusion
3	S-210226-00187	MASK BLACK (AFTER 5 WASHING CYCLES AT 60°C)	Pass
4	S-210226-00188	MASK BLACK (AFTER 20 WASHING CYCLES AT 60°C)	Pass
5	S-210226-00189	MASK BLACK (AFTER 30 WASHING CYCLES AT 60°C)	Pass
6	S-210226-00190	MASK BLACK (AFTER 40 WASHING CYCLES AT 60°C)	Pass
7	S-210226-00191	MASK BLACK (AFTER 50 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210226-00187	S-210226-00188	S-210226-00189	S-210226-00190
Average Differential pressure (Pa/cm ²)		<1	<1	<1	<1
Value 1 Differential pressure (Pa/cm ²)		<1	<1	<1	<1
Value 2 Differential pressure (Pa/cm ²)		<1	<1	<1	<1
Value 3 Differential pressure (Pa/cm ²)		<1	<1	<1	<1
Value 4 Differential pressure (Pa/cm ²)		<1	<1	<1	<1
Value 5 Differential pressure (Pa/cm ²)		<1	<1	<1	<1

	CAS	S-210226-00191
Average Differential pressure (Pa/cm ²)		<1
Value 1 Differential pressure (Pa/cm ²)		<1
Value 2 Differential pressure (Pa/cm ²)		<1
Value 3 Differential pressure (Pa/cm ²)		<1
Value 4 Differential pressure (Pa/cm ²)		<1
Value 5 Differential pressure (Pa/cm ²)		<1

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 °C and 85 ± 5 HR

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Note 9: 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

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

ID	ID AMSLab	Description	# Conclusion
18	S-210226-00202	MASK BLACK (ORIGINAL)	Pass

	CAS	S-210226-00202
(I.C. 95%) - Confidence Interval ±		0.0
Mean Value air permeability (l/m ² /seg)		>1000.0
Standard deviation		0.0
Value 10 (l/m ² /seg)		>1000.0
Value 1 (l/m ² /seg)		>1000.0
Value 2 (l/m ² /seg)		>1000.0
Value 3 (l/m ² /seg)		>1000.0
Value 4 (l/m ² /seg)		>1000.0
Value 5 (l/m ² /seg)		>1000.0
Value 6 (l/m ² /seg)		>1000.0
Value 7 (l/m ² /seg)		>1000.0
Value 8 (l/m ² /seg)		>1000.0
Value 9 (l/m ² /seg)		>1000.0

Notes:

Note 1: Applied standard UNE-EN 14683:2019 and European Specification CWA 17553:2020

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 °C 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:

- European specification CWA 17553:2020: >= 96 l/m²/s

Specific Notes:

(**) The result is out of specifications

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

ID	ID AMSLab	Description	# Conclusion
19	S-210226-00203	MASK BLACK (AFTER 5 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	# Conclusion
20	S-210226-00204	MASK BLACK (AFTER 20 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	# Conclusion
21	S-210226-00205	MASK BLACK (AFTER 30 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	# Conclusion
22	S-210226-00206	MASK BLACK (AFTER 40 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	# Conclusion
23	S-210226-00207	MASK BLACK (AFTER 50 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210226-00203	S-210226-00204	S-210226-00205	S-210226-00206
(I.C. 95%) - Confidence Interval ±		0.0	0.0	0.0	0.0
Mean Value air permeability (l/m2/seg)		>1000.0	>1000.0	>1000.0	>1000.0
Standard deviation		0.0	0.0	0.0	0.0
Value 10 (l/m2/seg)		>1000.0	>1000.0	>1000.0	>1000.0
Value 1 (l/m2/seg)		>1000.0	>1000.0	>1000.0	>1000.0
Value 2 (l/m2/seg)		>1000.0	>1000.0	>1000.0	>1000.0
Value 3 (l/m2/seg)		>1000.0	>1000.0	>1000.0	>1000.0
Value 4 (l/m2/seg)		>1000.0	>1000.0	>1000.0	>1000.0
Value 5 (l/m2/seg)		>1000.0	>1000.0	>1000.0	>1000.0
Value 6 (l/m2/seg)		>1000.0	>1000.0	>1000.0	>1000.0
Value 7 (l/m2/seg)		>1000.0	>1000.0	>1000.0	>1000.0
Value 8 (l/m2/seg)		>1000.0	>1000.0	>1000.0	>1000.0
Value 9 (l/m2/seg)		>1000.0	>1000.0	>1000.0	>1000.0

	CAS	S-210226-00207
(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

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Notes:

Note 1: Applied standard UNE-EN 14683:2019 and European Specification CWA 17553:2020

Note 2: Applied pressure: 100 Pa

Note 3: Applied area: 5 cm²Note 4: Report Unit: l/m²/seg (= mm/seg)

Note 5: Number of measurements: 10

Note 6: Conditioned samples: 24 hours at 20 ± 2 °C 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:

- European specification CWA 17553:2020: >= 96 l/m²/s

Specific Notes:

(**) The result is out of specifications

Issue Date: 29/03/2021

Signed: Manuel Lolo



amslab.
Applied Mass Spectrometry Laboratory S.L.
C.I.F. B: 27.380.914

General Manager

Signed: Pablo Perez



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Applied Mass Spectrometry Laboratory S.L.
C.I.F. B: 27.380.914

Chemical Lab Manager

Signed: Esteban Ramirez



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Applied Mass Spectrometry Laboratory S.L.
C.I.F. B: 27.380.914

Physical Lab Manager

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

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