



NIOSH Reference: TN-24263
Mfr. Reference: ALG02

National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051
October 30, 2020

Mr. Adam Harmon
President
ALG Health
2106 Baltimore Street
Defiance, OH 43512

Dear Mr. Harmon:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted September 23, 2020. This request was for approval of the model PT-N95C-02 air-purifying filtering facepiece respirator for protections against particulates at a N95 filter efficiency level. The complete respirator configuration is detailed on the assembly matrix, file name *ALG02AMa.xls*, revision A, dated: September 22, 2020.

The site qualification conducted on October 13 and October 14, 2020 at your facility in City of Defiance, Ohio and your responses to the Corrective Action Requests (CARs), specifically CARs 24263-01 through 24263-05 have been accepted and all the nonconformance issues related to the site qualification have been resolved.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired to be produced in languages other than English. Approval number TC-84A-9259 has been assigned. This respirator is approved for protection against particulates at N95 filter efficiency level.

NIOSH has also reviewed the Quality Procedure System presented and finds that this manual meets or exceeds the minimum technical requirements for quality assurance plans as outlined in Title 42, Code of Federal Regulations (CFR), Part 84.41(a) and, on the basis of this review, this quality manual is accepted.

The approval label is included as an attachment to this letter. The abbreviated label has been accepted as submitted. The cautions and limitations are listed on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely,

Jeffrey A.
Peterson -S

Digitally signed by
Jeffrey A. Peterson -S
Date: 2020.10.30
08:34:05 -04'00'

Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch

Enclosures

TEST REPORT

Task Number: TN-24263

Manufacturer: ALG Health

Prepared by: Nichole Suhon

Date: October 8, 2020

Tests Conducted by: Nichole Suhon

Respirator Tested: PT-N95C-02

Tests Completed

<u>Test Description</u>	<u>STP Number</u>
A. Exhalation Resistance Test	TEB-APR-STP-0003
B. Inhalation Resistance Test	TEB-APR-STP-0007
C. Sodium Chloride (NaCl) N95 Test	TEB-APR-STP-0059

Overall Results

The respirator system tested met the requirements of all the above procedures.

**National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet**



Task Number: TN-24263

Reference No.: CFR 84.172

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: ALG Health

Filter Type: Filter Only

Item Tested: PT-N95C-02

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Exhalation	Exhalation	
1	25	8.9	PASS
2	25	8.1	PASS
3	25	9.1	PASS

Overall Result: PASS

Comments:

Samples were tested on manometer 000286.

Was all equipment verified to be in calibration throughout all testing? Yes No

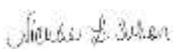
Signature:

Date: 10/8/2020

Engineering Technician

Task Number: TN-24263
Test: Exhalation Resistance Test
Manufacturer: ALG Health

Reference No.: CFR 84.172
STP No.: 3

Signature: 

Date: 10/8/2020

Engineering Technician

**National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet**



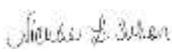
Task Number: TN-24263
Test: Inhalation Resistance Test
Manufacturer: ALG Health
Item Tested: PT-N95C-02

Reference No.: CFR 84.172
STP No.: 7

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Inhalation	Inhalation	
1	35	8.9	PASS
2	35	8.4	PASS
3	35	9.1	PASS

Overall Result: PASS

Signature: 

Date: 10/8/2020

Engineering Technician

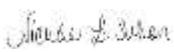
Task Number: TN-24263
Test: Inhalation Resistance Test
Manufacturer: ALG Health
Item Tested: PT-N95C-02

Reference No.: CFR 84.172
STP No.: 7

Comments:

Samples were tested on manometer 000034.

Was all equipment verified to be in calibration throughout all testing?	<input checked="" type="radio"/> Yes	<input type="radio"/> No
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Signature: 

Date: 10/8/2020

Engineering Technician

National Institute for Occupational Safety and Health
Evaluation and Testing Branch
Test Data Sheet



Task Number: TN-24263

Reference No.: CFR 84.174

Test: Sodium Chloride (NaCl) - N95

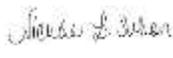
STP No.: 59

Manufacturer: ALG Health

Item Tested: PT-N95C-02

Filter	Flow Rate lpm	Initial Filter Resistance mm water gauge	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	9.3	5.00	1.060	1.060	PASS
2	85	11.6	5.00	1.940	1.940	PASS
3	85	10.9	5.00	0.663	0.663	PASS
4	85	9.8	5.00	0.785	0.785	PASS
5	85	10.8	5.00	0.769	0.769	PASS
6	85	10.4	5.00	0.904	0.904	PASS
7	85	9.8	5.00	1.260	1.260	PASS
8	85	10.2	5.00	0.864	0.864	PASS
9	85	10.6	5.00	0.734	0.734	PASS
10	85	10.8	5.00	0.830	0.830	PASS
11	85	10.1	5.00	0.945	0.945	PASS
12	85	10.3	5.00	0.887	0.887	PASS
13	85	11.5	5.00	2.500	2.500	PASS
14	85	9.7	5.00	1.228	1.228	PASS
15	85	9.5	5.00	1.640	1.640	PASS
16	85	9.2	5.00	0.715	0.715	PASS
17	85	9.8	5.00	1.101	1.101	PASS
18	85	10.9	5.00	0.844	0.844	PASS
19	85	10.0	5.00	0.849	0.849	PASS
20	85	9.3	5.00	1.276	1.276	PASS

Overall Result: PASS

Signature: 

Date: 10/8/2020

Task Number: TN-24263

Reference No.: CFR 84.174

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: ALG Health

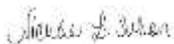
Item Tested: PT-N95C-02

Comments:

Samples 1-13 were tested on TIS 8130 machine 000333. Samples 14-20 were tested on TSI 8130A machine 000388. Flow rate is measured in liters/min. Resistance is measured in mm H₂O.

Was all equipment verified to be in calibration throughout all testing? Yes No

Signature:



Date: 10/8/2020

Engineering Technician

Form revision: 1.1 2 October 2019