

NIOSH Reference: TN-24345 Mfr. Reference: ALG01R Centers for Disease Control and Prevention (CDC)

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 December 8, 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 October 27, 2020. This request was for approval of the model PT-N95F-01 airpurifying 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 *ALG01RAMa.xls*, revision A, dated: October 20, 2020.

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-9275 has been assigned. This respirator is approved for protection against particulates at N95 filter efficiency level.

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).

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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 Peterson Chief, Conformity Verification and Standards Development Branch

Enclosures



National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory Evaluation and Testing Branch

TEST REPORT

Task Number: TN-24345

Manufacturer: ALG Health

Prepared by: Nichole Suhon

Date: December 3, 2020

Tests Conducted by: Nichole Suhon

Respirator Tested: PT-N95F-01

Tests Completed

Test Description		STP Number
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-24345 Reference No.: CFR 84.172

Test: Exhalation Resistance Test **STP No.:** 3

Manufacturer: ALG Health

Filter Type: Filter Only

Item Tested: PT-N95F-01

Sample	Maximum Allowable Resistance (MM of H2O) Exhalation	Actual Resistance (MM of H2O) Exhalation	Result
1	25	10.7	PASS
2	25	10.9	PASS
3	25	11.2	PASS

Overall Result: PASS

Comments:

Samples were tested on manometer 000286.

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

Signature: Date: 12/3/2020

Task Number: TN-24345 **Reference No.:** CFR 84.172

Test: Exhalation Resistance Test **STP No.:** 3

Manufacturer: ALG Health

Signature: Date: 12/3/2020

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



Task Number: TN-24345 Reference No.: CFR 84.172

Test: Inhalation Resistance Test **STP No.:** 7

Manufacturer: ALG Health **Item Tested:** PT-N95F-01

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Inhalation	Actual Resistance (MM of H2O) Inhalation	Result
1	35	11.7	PASS
2	35	12.7	PASS
3	35	13.2	PASS

Overall Result: PASS

Signature: Milled Little

Date: 12/3/2020

Task Number: TN-24345 Reference No.: CFR 84.172
Test: Inhalation Resistance Test STP No.: 7
Manufacturer: ALG Health
Item Tested: PT-N95F-01

Comments:

Samples were tested on manometer 000034.

Signature: Date: 12/3/2020

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



Task Number: TN-24345 Reference No.: CFR 84.174

Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59

Manufacturer: ALG Health **Item Tested:** PT-N95F-01

Filter	Flow Rate	Initial Filter Resistance mm water gauge	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	12.4	5.00	0.176	0.176	PASS
2	85	13.4	5.00	0.732	0.823	PASS
3	85	12.9	5.00	0.037	0.041	PASS
4	85	12.9	5.00	0.090	0.090	PASS
5	85	13.5	5.00	0.046	0.046	PASS
6	85	13.2	5.00	0.000	0.000	PASS
7	85	13.4	5.00	0.009	0.012	PASS
8	85	14.0	5.00	0.119	0.119	PASS
9	85	13.2	5.00	0.351	0.351	PASS
10	85	13.3	5.00	0.004	0.004	PASS
11	85	13.1	5.00	0.026	0.026	PASS
12	85	13.2	5.00	0.034	0.565	PASS
13	85	13.1	5.00	0.223	0.372	PASS
14	85	14.3	5.00	0.007	0.040	PASS
15	85	14.0	5.00	0.009	0.065	PASS
16	85	13.6	5.00	0.082	0.082	PASS
17	85	12.9	5.00	0.008	0.008	PASS
18	85	13.0	5.00	0.080	0.086	PASS
19	85	13.8	5.00	0.017	0.017	PASS
20	85	14.6	5.00	0.005	0.006	PASS

Overall Result: PASS

Signature: Date: 12/2/2020

Task Number: TN-24345 Reference No.: CFR 84.174

Test: Sodium Chloride (NaCl) - N95 STP No.: 59

Manufacturer: ALG Health **Item Tested:** PT-N95F-01

Comments:

Samples 1-12 were tested on TSI 8130 machine 000334. Samples 13-20 were tested on TSI 8130 machine 000333. 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	O No
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Signature: Date: 12/2/2020

Engineering Technician Form revision: 1.1 2 October 2019