

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Garry Galaxy Biotechnology Co., Ltd.

Model Tested: Respirator Mask With TruTone Technology

Date Tested: May 1, 2020

These findings pertain to the Garry Galaxy Biotechnology Co., Ltd., Respirator Mask With TruTone Technology. The product information provided with this product indicates that it meets GB/T 32610-2016 (the Chinese standard for Technical Specifications of Daily Protective Mask).

Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found [here](#).

A certificate of approval was not provided with the samples received; therefore, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 44.30% and 35.20%, respectively. All ten respirators measured less than 95%.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product's handling and exposures after leaving its manufacturer's control.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

This assessment is not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process. This assessment was developed as an assessment of the filter efficiency for those respirator's represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for [Crisis Capacity Strategies \(during known shortages\)](#).

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: May 1, 2020

Report Prepared: May 2, 2020

Manufacturer: Garry Galaxy Biotechnology Co., Ltd.

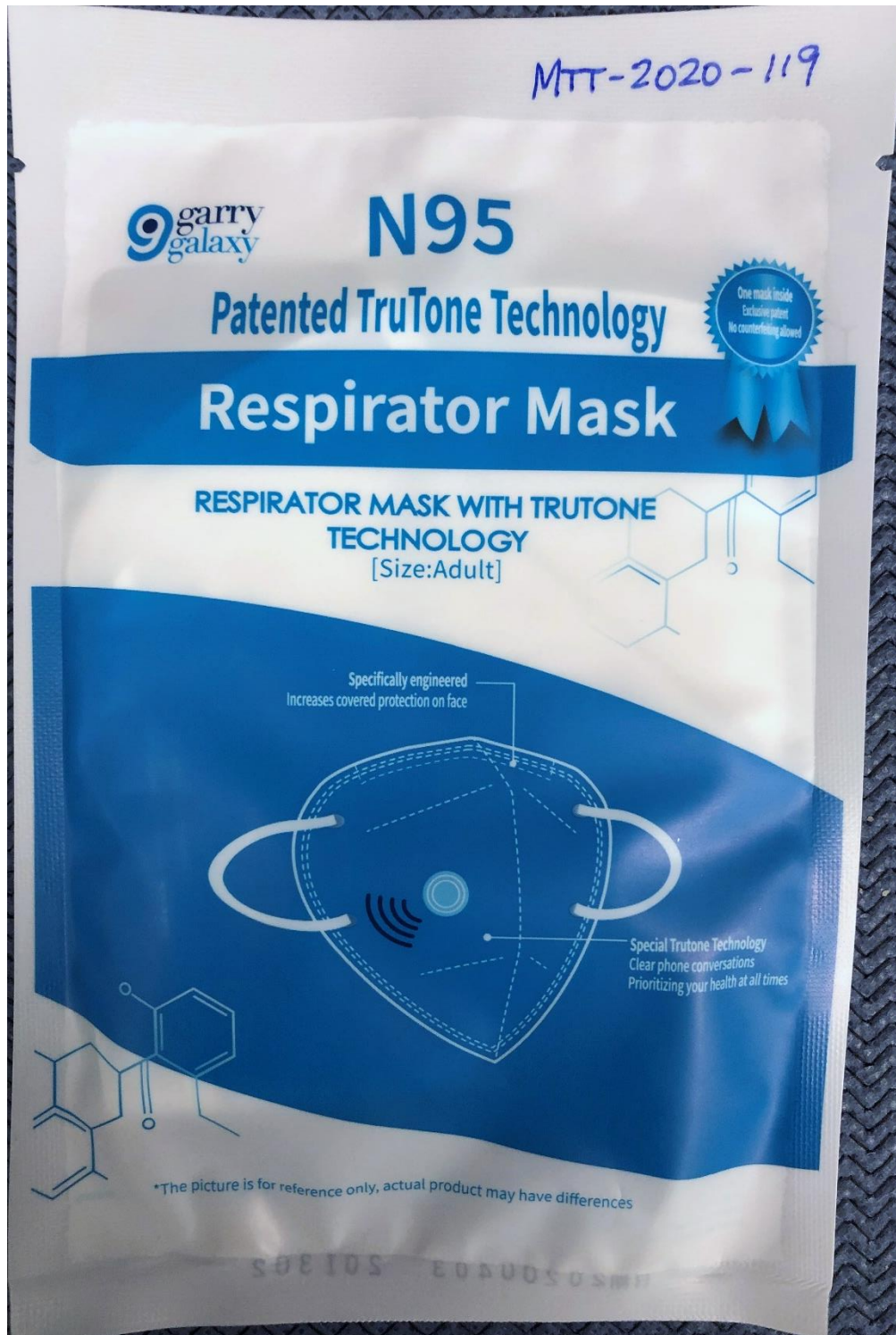
Item Tested: Respirator Mask With TruTone Technology

Country of Certification: China (GB/T 32610-2016)

Pictures have been added to the end of this report.

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	8.6	62.5	62.5	37.50
2	85	9.6	55.7	55.7	44.30
3	85	8.8	61.1	61.1	38.90
4	85	9.0	60.9	60.9	39.10
5	85	9.0	62.0	62.0	38.00
6	85	8.1	63.5	63.5	36.50
7	85	7.9	58.2	58.2	41.80
8	85	9.1	55.7	55.7	44.30
9	85	8.3	64.8	64.8	35.20
10	85	7.9	64.2	64.2	35.80
Minimum Filter Efficiency: 35.20			Maximum Filter Efficiency: 44.30		

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.



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[Uses]

- Protects you from contamination from cough, sneeze, or particulate matter such as pollen. Protection against bacteria, virus infection, and pollutants larger than 0.3 microns.
- Patented technology allows you to talk on the phone without removing the mask
- Place cellphone on the same side as the TruTone Technology stamp during phone calls

[User guide]

1. Tear open the package from the edge and take out the mask
2. Open up the mask
3. Hold the mask against facial area
4. Fasten the loops behind the ears, adjust the mask to comfortable position
5. Press the nose strip until it is tightly against the nose
6. When on the phone, place it on the same side as the TruTone stamp

[Product name] TruTone Technology Respirator Mask
[Life] 3 years
[Property and composition of the product] This product is made of clinically-used non-woven fabric
[Storage] Shall be stored in a well-ventilated room with less than 85% relative humidity and without corrosive gas
[Transportation] Shall avoid sunlight, rain, and mechanical damage
[Production date] See labeling on package
[Filtering efficiency] ≥95%
[Effective protection] Level A
[Contraindication] None
[Execution standard] GB/T 32610-2016
[Company name] Garry Galaxy Biotechnology Co., LTD
[Company address] Northwestern side of Tai Zhong Rd, Tai Er Zhuang District, ZaoZhuang City, China
[Production corporation] Garry Galaxy Biotechnology Co., LTD
[Production address] Northwestern side of Tai Zhong Rd, Tai Er Zhuang District, ZaoZhuang City, China
[Phone number] 400-992-0099
[Website] www.garrygalaxy.com
[Email] connect@garrygalaxy.com

[Note]
If the mask is broken, do not use and discard immediately. If the oxygen releasing capsule or the mask itself is damaged, do not use and discard immediately. The effective date of the mask is several uses after initial opening. Use immediately after opening packaging. When not in use, please store the mask into the resealable packaging. Keep the package sealed to maintain the best oxygen-releasing ability. This mask should never be rinsed or washed. If contaminated, please discard.

[Asia Patent Information]
China: ZL 2016 2 0577879.0
Taiwan: Invention No. 1644700
Korea: No. 10-1953988
Japan: No. 3213450
For patents in other regions, please contact the company

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