

# **Respirator qualitative fit test using 3M<sup>®</sup> FT-30 fit test apparatus** Copyright © 2024 Viral and Human Genomics BSL-3 Laboratory, UASLP Faculty of Medicine, San Luis Potosi, Mexico.

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This protocol outlines the standard procedure for conducting qualitative fit testing of N95 respirators using the 3M FT-30 Fit Test Apparatus (Bitter), in accordance with the manufacturer's instructions. The method employs Denatonium Benzoate, a non-toxic compound with an intensely bitter taste, as the test aerosol. The purpose of this protocol is to ensure that laboratory personnel receive appropriate training in the correct donning, adjustment, and use of N95 respirators, and to verify that each individual achieves an adequate facial seal during use. During the test, individuals are exposed to a bitter mist while performing a series of standardized exercises that simulate workplace movements and conditions. It is important to distinguish between the sensitivity solution and the fit test solution, both of which are used during the procedure. The sensitivity solution is a significantly diluted formulation (typically  $\sim 0.0175\%$ ) used to confirm the test subject's ability to detect the bitter taste. The fit test solution, by contrast, is more concentrated (typically  $\sim 0.2\%$ ) and is used to evaluate whether any leakage occurs through the respirator seal under simulated working conditions.

#### **Preparations**

- 1) To prepare the sensitivity threshold solution, dissolve 5 grams of sodium chloride (NaCl) in 100 mL of double-distilled water. Once fully dissolved, add 13.5 milligrams of denatonium benzoate and mix until completely incorporated.
- 2) To prepare the fit test solution, dissolve 5 grams of sodium chloride (NaCl) in 100 mL of double-distilled water. Once fully dissolved, add 169 milligrams of denatonium benzoate and mix until completely incorporated.
- 3) Assemble hood and collar and tighten drawstring.
- 4) Pour 4 ml of the sensitivity threshold solution into the nebulizer labelled "Sensitivity Test Solution".
- 5) Pour 4 ml of the fit test solution into the nebulizer labelled "**Fit Test Solution**".
- 6) Ask all test subjects to refrain from eating, drinking (except plain water), smoking, or chewing gum for at least 15 minutes prior to the fit test to ensure accurate results.
- 7) The lab manager should instruct all test subjects on the correct procedure for respirator donning (putting on), doffing (taking off), use, care, and disposal.
- 8) All personnel who routinely wear eye protection must also wear it during the fit test to ensure it does not interfere with the respirator's seal and that testing reflects actual working conditions.
- 9) Facial hair must not interfere with the seal of the respirator (see the corresponding infographic).



#### Procedure for sensitivity threshold test

To confirm that the person can detect the test agent (in this case, the bitter taste of Bitrex, which is denatonium benzoate). Some people may have reduced taste sensitivity or individual variation in taste thresholds, so it's critical to check that the test subject can detect even a small amount of the solution before the actual test begins. If they can't taste it, the qualitative method is invalid for that person (and a quantitative fit test is recommended instead).

- 1. Position the test hood over the subject's head without the respirator in place.
- 2. Instruct the subject to breathe through the mouth with the tongue slightly extended, ensuring a steady and natural breathing pattern.
- 3. Connect the nebulizer with sensitivity threshold solution to the lowest port of the test hood.
- 4. Instruct the subject to raise their left hand immediately upon detecting a bitter taste on the tongue.
- 5. Begin administering single nebulizations of the sensitivity threshold solution into the hood, waiting approximately 5 seconds between each squeeze of the nebulizer.
- 6. Record the total number of nebulizations required for the subject to perceive the bitter taste in the corresponding form.
- 7. If the subject does not detect a bitter taste after 30 nebulizations, they should be considered bitterinsensitive and must be assessed using the sweet (saccharin-based) solution as an alternative.
- 8. If the bitter taste is detected within 30 nebulizations, remove the hood and allow the subject to recover for at least 5 minutes. Ventilate the area as needed. The subject may rinse their mouth with water to eliminate residual bitterness. Once recovered, proceed to the fit test.



#### **Procedure for fit test**

The more concentrated fit test solution is used during the formal fit testing exercises—such as speaking, head movements, and bending—to evaluate the effectiveness of the respirator's seal. If the test subject detects a bitter taste (Bitrex), it indicates that the aerosolized test agent has penetrated the respirator, signifying an inadequate seal and a failed fit test.

- 1. Instruct the test subject to don the N95 respirator according to manufacturer instructions or as previously trained. Additional personal protective equipment (PPE), such as safety goggles, should also be worn if typically used during routine activities.
- 2. Once the respirator is properly positioned, place the test hood over the subject's head.
- 3. Ask the subject to maintain their mouth slightly open and tongue extended throughout all exercises to facilitate detection of the bitter aerosol.
- 4. Administer at least 10 full compressions of the Fit Test Solution by connecting the nebulizer to the upper hood port nebulizer's test port, or half the number of nebulizations determined during the sensitivity screening (if greater than 10).
- 5. The subject should breathe normally for 30 seconds with mouth open, and tongue extended. After this time, administer an additional half-dose of the required number of nebulizations to maintain aerosol concentration (or the standard 5 nebulization's) and allow subject to breathe normally for another 30 seconds.
- 6. Repeat the same procedure as above while the subject performs slow, deep breaths. Administer additional nebulizations after 30 seconds.
- 7. Instruct the subject to slowly turn their head from side to side, pausing briefly at each extreme (left and right), while breathing through the open mouth with tongue extended. Administer additional nebulizations after 30 seconds.
- 8. Instruct the subject to slowly nod their head up and down, pausing at each end of the movement, while maintaining an open mouth and extended tongue. Administer additional nebulizations after 30 seconds.
- 9. Ask the subject to recite a random fragment of text in a loud, clear, audible voice. The mouth must remain open, and tongue extended while speaking. Administer additional nebulizations after 30 seconds.
- 10. Instruct the subject to bend at the waist and breathe normally for 30 seconds with mouth open and tongue extended. Administer additional nebulizations after 30 seconds.



### **Test result interpretation**

- 1. At any point during the fit test exercises, if the test subject detects a bitter taste, this indicates that aerosolized Denatonium Benzoate (Bitrex) has breached the respirator seal, entering the breathing zone. In such cases, the fit test is considered a failure, and the following steps must be taken:
- 2. Instruct the subject to immediately stop the test and remove the fit test hood.
- 3. Document the exercise phase during which the bitter taste was first detected.
- 4. Reassess the donning technique and fit of the respirator. Check for improper strap tension, facial hair interference, or incorrect positioning.
- 5. Allow the subject to rest and rinse the mouth with water, reattempt the fit test only after 15 minutes have elapsed.
- 6. Assess whether the same model of respirator should be used or not.
- 7. If test subject does not detect bitter taste during all seven exercises the fit test is considered a pass. This indicates that the respirator provides an adequate facial seal under working conditions.
- 8. If the test subject continues detecting the bitter taste, suspend testing and reschedule for another time.
- 9. All fit test results—pass or fail—must be documented in the subject's fit test record and subjects should receive a copy of their result.

## References

- 1. CDC Personal Protective Equipment Fit testing, Feb 2, 2025 www.cdc.gov/niosh/ppe/respirators/fit-testing.html
- 2. CDC Personal Protective Equipment Filtering Facepiece Respirators, Feb 2, 2025 www.cdc.gov/niosh/ppe/respirators/ffr.html
- 3. CDC Personal Protective Equipment Respirator Types and Use, Mar 04, 2025 www.cdc.gov/niosh/ppe/respirators/index.html
- 4. CDC Personal Protective Equipment Respirator Selection and Use, Feb 03, 2025 www.cdc.gov/niosh/ppe/respirators/selection.html
- 5. Occupational Safety and Health Administration Respiratory Protection <u>www.osha.gov/respiratory-protection/training</u>



Implementing fit testing for N95 filtering facepiece respirators: Practical information from a large cohort of hospital workers. E. McMahon, K. Wada, A. Dufresne. Am J Infect Control. 2008 May; 36(4): 298–300. Published online 2008 Apr 30. doi: 10.1016/j.ajic.2007.10.014.

## **Revision history**

- 1. Original document.
- 2. Added references and document format changes.
- 3. Rephrased document instructions to align with SOPs.