Evaluation of alternative methods to quantitative fit testing for the protection of healthcare workers – SARS-CoV-2 (COVID-19 disease)

SBAR

Situation:

Due to a lack of PPE, in particular, tight fitting facepiece respirators, fit testing should move to a method that does not destroy the respirator, as quantitative fit testing does.
Therefore the method of qualitative fit testing may be preferred during the SARS-CoV-2 pandemic as a way to conserve respirators that are in short supply, and protect workers. There is now a concern that the solutions required for qualitative fit testing (mainly Bitrex™) may be of limited supply at present.

Background:

Respirator fit test methods are classified as either qualitative or quantitative, and there are multiple protocols of each classification that are NIOSH-recommended or meet the requirements of OSHA's Respiratory Protection Standard.
A qualitative fit test is a pass/fail test to assess the adequacy of respirator fit that relies on the individual's sensory detection of a test agent.
A quantitative fit test numerically measures the effectiveness of the respirator to seal with the wearer's face, without relying on the wearer's voluntary or involuntary response to a test agent. Quantitative fit tests involve adaptation of the respirator to the fit testing equipment, which can involve making holes in the respirator.
Many healthcare systems already use qualitative fit test methods for fit testing HCP. For those using quantitative fit test methods, considerations can be made to use qualitative fit test methods to minimize the destruction of an N95 respirator used in fit testing and allow for the re-use of the same N95 respirator by the HCP.

Assessment:

Method	Effective for	ECRI Recommendations
Irritant Smoke (Stannic Chloride) Protocol	P100, HEPA or higher	Recommended for fit testing if filtering equipment: P100, HEPA or higher is being used (some PAPRs)
Isoamyl Acetate Protocol	N95 or higher **Respirator must be equipped with an organic vapor filter.**	**Not** recommended for fit testing in healthcare for SARS-CoV-2
Saccharin Solution Aerosol Protocol	N95 or higher	Recommended/preferred
Bitrex™ (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol	N95 or higher	Recommended/preferred

5200 Butler Pike, Plymouth Meeting, PA 19462
e clientservices@ecri.org | w www.ecri.org

Recommendation:

1. Given the limited availability and proprietary nature of Bitrex™ at the present time, Saccharin solution would be an acceptable alternative to Bitrex™ for use in qualitative fit testing protocols
2. Saccharin and Bitrex™ fit testing protocols are very similar, including testing equipment. Therefore a recommendation is made to use Saccharin or Bitrex™ based on availability, in order to make a good faith effort to comply with 29 CFR § 1910.134

   A. Bitrex™ consists of Denatonium Benzoate USP and is available in powder for compounding/mixing. See test protocols for concentrations.
   B. Sodium saccharin USP is available in powder for compounding/mixing. See test protocols for concentrations.

3. Consider compounding/mixing recommended test solutions for fit testing use, if not available in commercially ready to use forms. Comply with USP standards 795, 797 as applicable.
4. If the above recommendations related to qualitative fit testing, in order to conserve respirators, cannot be achieved based on fit testing solution or raw component availability, and every effort is made to provide a good-faith effort at complying with 29 CFR§1910.134(f)(2), and is documented as such, then a facility may consider temporary suspension of fit testing during the SAR-CoC-2 pandemic period as per the temporary enforcement guidance.

Detailed SBAR

Situation:

Due to a lack of PPE, in particular, tight fitting facepiece respirators, fit testing should move to a method that does not destroy the respirator, as quantitative fit testing does.
Therefore the method of qualitative fit testing may be preferred during the SARS-CoV-2 pandemic as a way to conserve respirators that are in short supply, and protect workers. There is now a concern that the solutions required for qualitative fit testing (mainly Bitrex™) may be of limited supply at present.

Background:

Respirator fit test methods are classified as either qualitative or quantitative, and there are multiple protocols of each classification that are NIOSH-recommended or meet the requirements of OSHA's Respiratory Protection Standard.
A qualitative fit test is a pass/fail test to assess the adequacy of respirator fit that relies on the individual's sensory detection of a test agent.
A quantitative fit test numerically measures the effectiveness of the respirator to seal with the wearer's face, without relying on the wearer's voluntary or involuntary response to a test agent. Quantitative fit tests involve adaptation of the respirator to the fit testing equipment, which can involve making holes in the respirator.
Many healthcare systems already use qualitative fit test methods for fit testing HCP. For those using quantitative fit test methods, considerations can be made to use qualitative fit test methods to minimize the destruction of an N95 respirator used in fit testing and allow for the re-use of the same N95 respirator by the HCP.
In March 2020, OSHA recommended healthcare employers consider changing from a quantitative fit testing method to a qualitative fit testing method. Qualitative fit methods may

also allow for rapid fit testing of larger numbers of HCP. Any switch in methods should be assessed to ensure proficiency of the fit testers in carrying out the test.
Facilities can consider temporarily suspending annual fit testing of HCP in times of expected shortages. In March 2020, OSHA issued new temporary guidance regarding the enforcement of OSHA's Respiratory Protection Standard. The guidance gave OSHA field offices enforcement discretion concerning the annual fit testing requirement as long as HCP have undergone an initial fit test with the same model, style, and size. Other conditions include explaining to HCP the importance of conducting a user seal check each time the respirator is put on and conducting a fit test if there are visual changes to the employee's physical condition.
The suspension of fit testing may take place if:
1. If the HCP has had an initial fit test with the same model, size, and style respirator, a fit test is not necessary as per the OSHA temporary guidance from March 2020.
2. The facility has made a good-faith effort to comply with 29 CFR§1910.134(f)(2)
3. Use only NIOSH-certified respirators; - however on March 28, 2020 the FDA reissued the letter that discussed non-NOSH approved respirator models from other countries https://www.fda.gov/media/136403/download
4. Implement CDC and OSHA strategies for optimizing the supply of N95 filtering facepiece respirators and prioritize their use.
5. **Perform initial fit tests for each HCP with the same model, style, and size respirator that the worker will be required to wear for protection against** COVID-19 (initial fit testing is essential to determine if the respirator properly fits the worker and is capable of providing the expected level of protection) This would be of particular importance if supplemental masks from stockpile or other suppliers differed from the model, style, and size initially fitted to the HCP.
6. Inform workers that the employer is temporarily suspending the annual fit testing of N95 filtering facepiece respirators to preserve and prioritize the supply of respirators for use in situations where they are required to be worn
7. Explain to workers the importance of performing a user seal check (i.e., a fit check) at each donning to make sure they are getting an adequate seal from their respirator, in accordance with the procedures outlined in 29 CFR § 1910.134, Appendix B-1, User Seal Check Procedures.4
8. Conduct a fit test if they observe visual changes in the employee's physical condition that could affect respirator fit (e.g., facial scarring, dental changes, cosmetic surgery, or obvious changes in body weight) and explain to workers that, if their face shape has changed since their last fit test, they may no longer be getting a good facial seal with the respirator and, thus, are not being adequately protected; and,
9. Remind workers that they should inform their supervisor or their respirator program administrator if the integrity and/or fit of their N95 filtering facepiece respirator is compromised.

Description of qualitative fit testing methods/procedures

Qualitative fit testing methods/procedures
1. General
(a) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order.
(b) The employer shall ensure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

Note: This protocol is not appropriate to use for the fit testing of particulate respirators. If used to fit test particulate respirators**, the respirator must be equipped with an organic vapor filter.**

(a) Odor Threshold Screening

Odor threshold screening, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate at low levels.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor-free water (e.g., distilled or spring water) at approximately 25 °C (77 °F) shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 ml of pure IAA to 800 ml of odor-free water in a 1 liter jar, closing the lid and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well-ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(5) The odor test solution is prepared in a second jar by placing 0.4 ml of the stock solution into 500 ml of odor-free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor-free water.

(7) The odor test and test blank jar lids shall be labeled (e.g., 1 and 2) for jar identification. Labels shall be placed on the lids so that they can be peeled off periodically and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): "The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl Acetate Fit Test

(1) The fit test chamber shall be a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. If no drum liner is available, a similar chamber shall be constructed using plastic sheeting. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold

screening and respirator selection, and shall be well-ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.
(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.
(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 ml of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber. An IAA test swab or ampule may be substituted for the IAA wetted paper towel provided it has been demonstrated that the alternative IAA source will generate an IAA test atmosphere with a concentration equivalent to that generated by the paper towel method.
(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test exercises; or to demonstrate some of the exercises.
(7) If at any time during the test, the subject detects the banana-like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.
(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (b) (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait at least 5 minutes before retesting. Odor sensitivity will usually have returned by this time.
(9) If the subject passes the test, the efficiency of the test procedure shall be demonstrated by having the subject break the respirator face seal and take a breath before exiting the chamber.
(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so that there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self-sealing plastic bag to keep the test area from being contaminated.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.
(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.
(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.
(2) The test enclosure shall have a 3/4 -inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.
(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a sweet taste.
(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the threshold check solution into the enclosure. The nozzle is directed away from the

nose and mouth of the person. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.
(5) The threshold check solution is prepared by dissolving 0.83 gram of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution (see (b)(5) below) in 100 ml of distilled water.
(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.
(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted. If the test subject reports tasting the sweet taste during the ten squeezes, the screening test is completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.
(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.
(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the third set of ten squeezes, the screening test is completed. The taste threshold is noted as thirty regardless of the number of squeezes actually completed.
(10) The test conductor will take note of the number of squeezes required to solicit a taste response.
(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject is unable to taste saccharin and may not perform the saccharin fit test.
Note to paragraph 3(a): If the test subject eats or drinks something sweet before the screening test, he/she may be unable to taste the weak saccharin solution.
(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.
(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.
(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.
(b) Saccharin solution aerosol fit test procedure.
(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.
(2) The fit test uses the same enclosure described in 3. (a) above.
(3) The test subject shall don the enclosure while wearing the respirator selected in section I. A. of this appendix. The respirator shall be properly adjusted and equipped with a particulate filter(s).
(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.
(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.
(6) As before, the test subject shall breathe through the slightly open mouth with tongue extended, and report if he/she tastes the sweet taste of saccharin.
(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of saccharin fit test solution is sprayed into the enclosure using the same number

of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test. A minimum of 10 squeezes is required.
(8) After generating the aerosol, the test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.
(9) Every 30 seconds the aerosol concentration shall be replenished using one half the original number of squeezes used initially (e.g., 5, 10 or 15).
(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected. If the test subject does not report tasting the saccharin, the test is passed.
(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and the test is failed. A different respirator shall be tried and the entire test procedure is repeated (taste threshold screening and fit testing).
(12) Since the nebulizer has a tendency to clog during use, the test operator must make periodic checks of the nebulizer to ensure that it is not clogged. If clogging is found at the end of the test session, the test is invalid.

4. Bitrex™ (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol

The Bitrex™ (Denatonium benzoate) solution aerosol QLFT protocol uses the published saccharin test protocol because that protocol is widely accepted. Bitrex is routinely used as a taste aversion agent in household liquids which children should not be drinking and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste Threshold Screening.

The Bitrex taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of Bitrex.
(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches (30.5 cm) in diameter by 14 inches (35.6 cm) tall. The front portion of the enclosure shall be clear from the respirator and allow free movement of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.
(2) The test enclosure shall have a 3/4 inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.
(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his or her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a bitter taste.
(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the Threshold Check Solution into the enclosure. This Nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.
(5) The Threshold Check Solution is prepared by adding 13.5 milligrams of Bitrex to 100 ml of 5% salt (NaCl) solution in distilled water.
(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that the bulb collapses completely, and is then released and allowed to fully expand.
(7) An initial ten squeezes are repeated rapidly and then the test subject is asked whether the Bitrex can be tasted. If the test subject reports tasting the bitter taste during the ten squeezes, the screening test is completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted. If the test subject reports tasting the bitter taste during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.
(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted. If the test subject reports tasting the bitter taste during the third set of ten squeezes, the screening test is completed. The taste threshold is noted as thirty regardless of the number of squeezes actually completed.
(10) The test conductor will take note of the number of squeezes required to solicit a taste response.
(11) If the Bitrex is not tasted after 30 squeezes (step 10), the test subject is unable to taste Bitrex and may not perform the Bitrex fit test.
(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.
(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.
(14) The nebulizer shall be thoroughly rinsed in water, shaken to dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Bitrex Solution Aerosol Fit Test Procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.
(2) The fit test uses the same enclosure as that described in 4. (a) above.
(3) The test subject shall don the enclosure while wearing the respirator selected according to section I. A. of this appendix. The respirator shall be properly adjusted and equipped with any type particulate filter(s).
(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.
(5) The fit test solution is prepared by adding 337.5 mg of Bitrex to 200 ml of a 5% salt (NaCl) solution in warm water.
(6) As before, the test subject shall breathe through his or her slightly open mouth with tongue extended, and be instructed to report if he/she tastes the bitter taste of Bitrex.
(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of the fit test solution is sprayed into the enclosure using the same number of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test.
(8) After generating the aerosol, the test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.
(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes used initially (e.g., 5, 10 or 15).
(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of Bitrex is detected. If the test subject does not report tasting the Bitrex, the test is passed.
(11) If the taste of Bitrex is detected, the fit is deemed unsatisfactory and the test is failed. A different respirator shall be tried and the entire test procedure is repeated (taste threshold screening and fit testing).

5. Irritant Smoke (Stannic Chloride) Protocol

This qualitative fit test uses a person's response to the irritating chemicals released in the "smoke" produced by a stannic chloride ventilation smoke tube to detect leakage into the respirator.
(a) General Requirements and Precautions
(1) The respirator to be tested shall be **equipped with high efficiency particulate air (HEPA) or P100 series filter(s).**
(2) Only stannic chloride smoke tubes shall be used for this protocol.
(3) No form of test enclosure or hood for the test subject shall be used.
(4) The smoke can be irritating to the eyes, lungs, and nasal passages. The test conductor shall take precautions to minimize the test subject's exposure to irritant smoke. Sensitivity varies, and certain individuals may respond to a greater degree to irritant smoke. Care shall be taken when performing the sensitivity screening checks that determine whether the test subject can detect irritant smoke to use only the minimum amount of smoke necessary to elicit a response from the test subject.
(5) The fit test shall be performed in an area with adequate ventilation to prevent exposure of the person conducting the fit test or the build-up of irritant smoke in the general atmosphere.
(b) Sensitivity Screening Check
The person to be tested must demonstrate his or her ability to detect a weak concentration of the irritant smoke.
(1) The test operator shall break both ends of a ventilation smoke tube containing stannic chloride, and attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute, or an aspirator squeeze bulb. The test operator shall cover the other end of the smoke tube with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.
(2) The test operator shall advise the test subject that the smoke can be irritating to the eyes, lungs, and nasal passages and instruct the subject to keep his/her eyes closed while the test is performed.
(3) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties and to determine if he/she can detect the irritating properties of the smoke. The test operator shall carefully direct a small amount of the irritant smoke in the test subject's direction to determine that he/she can detect it.
(c) Irritant Smoke Fit Test Procedure
(1) The person being fit tested shall don the respirator without assistance, and perform the required user seal check(s).
(2) The test subject shall be instructed to keep his/her eyes closed.
(3) The test operator shall direct the stream of irritant smoke from the smoke tube toward the faceseal area of the test subject, using the low flow pump or the squeeze bulb. The test operator shall begin at least 12 inches from the facepiece and move the smoke stream around the whole perimeter of the mask. The operator shall gradually make two more passes around the perimeter of the mask, moving to within six inches of the respirator.
(4) If the person being tested has not had an involuntary response and/or detected the irritant smoke, proceed with the test exercises.
(5) The exercises identified in section I.A. 14. of this appendix shall be performed by the test subject while the respirator seal is being continually challenged by the smoke, directed around the perimeter of the respirator at a distance of six inches.
(6) If the person being fit tested reports detecting the irritant smoke at any time, the test is failed. The person being retested must repeat the entire sensitivity check and fit test procedure.

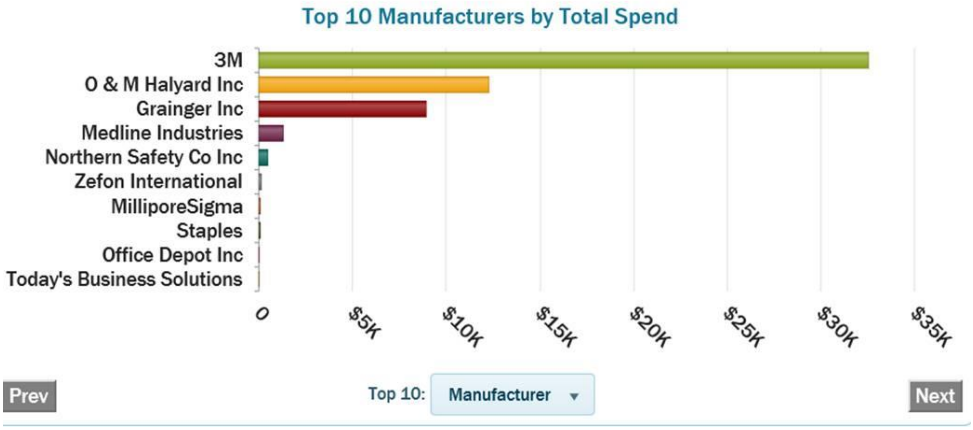
(7) Each test subject passing the irritant smoke test without evidence of a response (involuntary cough, irritation) shall be given a second sensitivity screening check, with the smoke from the same smoke tube used during the fit test, once the respirator has been removed, to determine whether he/she still reacts to the smoke. Failure to evoke a response shall void the fit test.
(8) If a response is produced during this second sensitivity check, then the fit test is passed.

Assessment:

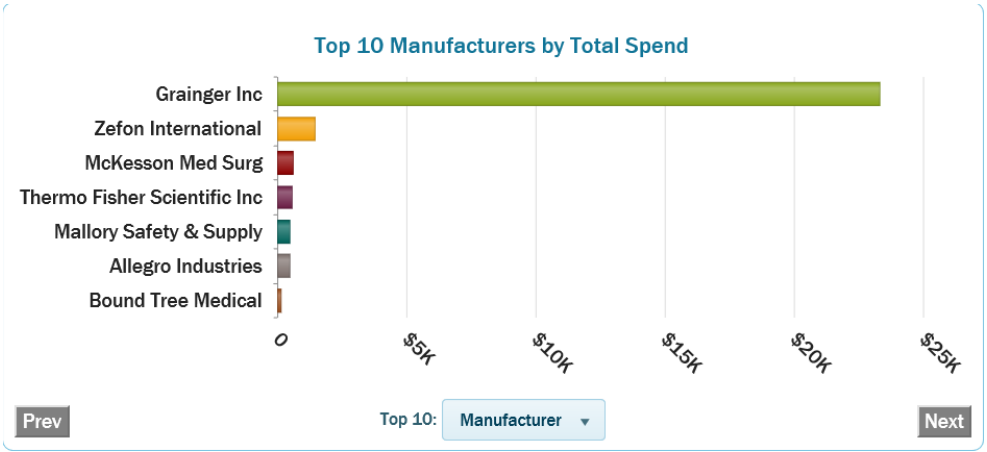
Method	Effective for	ECRI Recommendations
Irritant Smoke (Stannic Chloride) Protocol	P100, HEPA or higher	Recommended for fit testing if filtering equipment: P100, HEPA or higher is being used (some PAPRs)
Isoamyl Acetate Protocol	N95 or higher **Respirator must be equipped with an organic vapor filter.**	**Not** recommended for fit testing in healthcare for SARS-CoV-2
Saccharin Solution Aerosol Protocol	N95 or higher	Recommended/preferred
Bitrex™ (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol	N95 or higher	Recommended/preferred

Manufacturers by spend

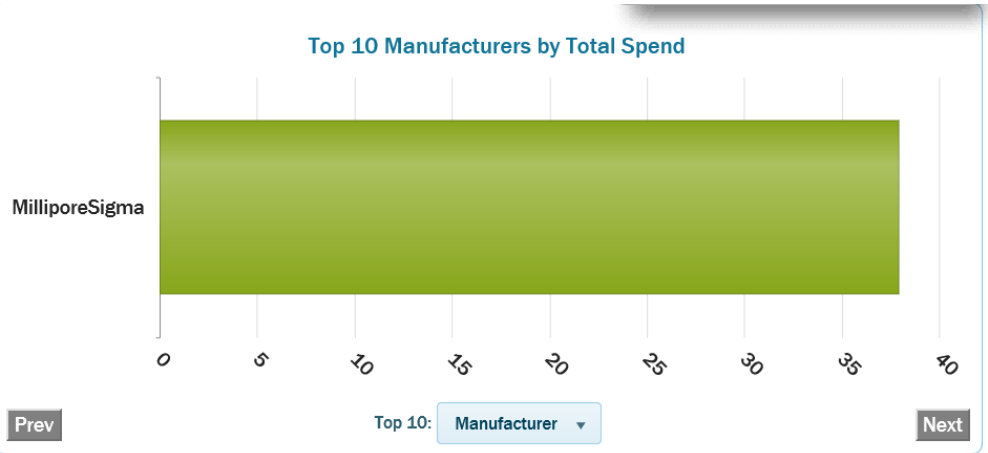
Sodium Saccharin USP:



Bitrex™:



Denatonium Benzoate USP:



Recommendations:

1. Given the limited availability and proprietary nature of Bitrex™ at the present time, Saccharin solution would be an acceptable alternative to Bitrex™ for use in qualitative fit testing protocols
2. Saccharin and Bitrex™ fit testing protocols are very similar, including testing equipment. Therefore a recommendation is made to use Saccharin or Bitrex™ based on availability, in order to make a good faith effort to comply with 29 CFR § 1910.134

C. Bitrex™ consists of Denatonium Benzoate USP and is available in powder for compounding/mixing. See test protocols for concentrations.

D. Sodium saccharin USP is available in powder for compounding/mixing. See test protocols for concentrations.

3. Consider compounding/mixing recommended test solutions for fit testing use, if not available in commercially ready to use forms. Comply with USP standards 795, 797 as applicable.
4. If the above recommendations related to qualitative fit testing, in order to conserve respirators, cannot be achieved based on fit testing solution or raw component availability, and every effort is made to provide a good-faith effort at complying with 29 CFR§1910.134(f)(2), and is documented as such, then a facility may consider temporary suspension of fit testing during the SAR-CoC-2 pandemic period as per the temporary enforcement guidance.

Notes:

1. CDC COVID-19 Strategies for Optimizing the Supply of N95 Respirators https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html
2. U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 4, 2020). U.S. Department of Health and Human Services, Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564 of the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. March 2, 2020. https://www.fda.gov/media/136403/download
3. USP General Chapter 795, 797 Pharmaceutical Compounding https://www.usp.org/compounding
4. The National Personal Protective Technology Laboratory (NPPTL) Healthcare respiratory Protection Resources Fit Testing NIOSH Documents. https://www.cdc.gov/niosh/npptl/hospresptoolkit/fittesting.html
5. United states department of labor. Occupational Safety and Health Administration. Temporary Enforcement Guidance - Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces during the COVID-19 Outbreak https://www.osha.gov/memos/2020-03-14/temporary-enforcement-guidance-healthcare-respiratory-protection-annual-fit
6. United states department of labor. Occupational Safety and Health Administration. 1910.134 - Respiratory Protection. https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134