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ABSTRACT

Laboratory Protocol
Fit test procedure

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ABSTRACT

Laboratory Protocol
Fit test procedure

The new silicone N99 half-piece respirator, VJR-N04454606MU N99: A novel and effective tool to prevent COVID-19

Protocol Number 1

Trial Registration

NCT044454606

Study conducted by

Navamindradhiraj University

Source of funding

The National Research Council of Thailand ,The National Science Technology and Development Agency and Navamindradhiraj University.

Site Principle Investigator

Associate Professor Anan Manomaipiboon

Version Date

20 October 2020

Confidentiality Statement

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Investigator's Agreement Page

1. I have read the foregoing protocol and agree to conduct the study as outlined herein.
2. I agree to follow this protocol version as approved by the Ethics Review Committee/Institutional Review Board (ERC/IRB).
3. I agree this study will be conducted in accordance and in conformity with ICH GCP, the Declaration of Helsinki, and all applicable regulations.
4. I will conduct the study in accordance with applicable ERC/IRB requirements to maintain the protection of the rights and welfare of study participants.
5. I certify that I, and the study staff, have received the requisite training to conduct this research protocol.
6. I will not modify the protocol without first obtaining permission from the sponsor, an ERC/IRB approved amendment, and new protocol version, unless modification is necessary to protect the health and welfare of study participants.
7. I will ensure the data and/or specimens are maintained in accordance with the data and/or specimen disposition outlined in the protocol. Any modifications to this plan should first be reviewed and approved by the applicable ERC/IRB.
8. I will prepare and submit continuing review reports according to established timeframes at intervals established by the IRB and a study closure report when all research activities are completed.
9. I agree to maintain adequate and accurate records in accordance with institutional policies, local laws, and regulations as applicable.
10. I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept the responsibility for the scientific conduct of the project.

XXX (PI)DateXXX

Bitrex Qualitative fit test

Reference: https://www.moldex.com/pdf/misc/bitrex_fit_test_kit.pdf

According to the manufacturer's instructions, we used the Bitrex fit test to ensure the good fit and seal of the respirator to the wearer. This fit test meets the performance criteria for fit testing respirators under current OSHA Standards.

- The equipment required are

1. Moldex Bitrex Qualitative Fit Test Kit
2. Moldex Bitrex Quantative Test Hood
3. Nebulizer #1 (BITREX Sensitivity Solution)
4. Nebulizer #2 (BITREX Fit Test Solution)
6. BITREX Fit Test Solution Applicator Tube
7. BITREX Sensitivity Solution Applicator Tube
8. Appropriate Moldex Respirators*

5. Two sets Replacement Nebulizer Inserts

We followed the manufacturer guidelines as following;

1. Sensitivity screening

Each subject was given a taste-threshold screening test to ensure that he or she could taste Bitrex at the specified solution to make the fit test valid.

- 1) Ensure that the test subject does not eat, drink, smoke or chew gum for 15 minutes before the test.
- 2) Explain the screening and fit testing procedures to the subject.
- 3) Instruct subject to put on the hood without a respirator.
- 4) Position the hood forward so there is about six inches between the subject's face and the window. This is especially important for the fit test. It allows free movement of the head when the subject is wearing a respirator and helps ensure even dispersion of the aerosol around the face seal area.
- 5) Instruct the test subject to breathe with their mouth slightly open and tongue extended.
- 6) Using the nebulizer labeled BITREX Sensitivity Solution, inject the aerosol into the hood through the hole in front of the enclosure. Inject ten (10) squeezes of the bulb, fully collapsing and fully expanding the bulb on each squeeze.
- 7) Ask the subject if he can detect the bitter taste of BITREX.
- 8) If the subject does not detect bitter taste, inject an additional ten squeezes into the hood.
- 9) If the subject still does not detect bitter taste, inject an additional ten squeezes, for a total of 30 squeezes.
- 10) If 30 squeezes were inadequate to elicit a response from the subject, this subject cannot be fit tested with the BITREX test.
- 11) If the subject could detect bitter taste, the number of squeezes required to produce a taste response should be noted, i.e., 10, 20 or 30 squeezes, even if subject tasted the BITREX on a number of squeezes other than multiples of ten.
- 12) Remove the hood. Wait a few minutes, to give the subject time to clear the taste from his mouth, before proceeding to the fit test. A drink of water during this time will aid in removing the bitter taste. Use a paper towel to wipe the subject's mouth of any residue (also wipe mustaches).

The Fit test procedure

2. Fit test

- 1) Use any Moldex disposable N, R or P series class disposable respirator or any Moldex half mask or full face respirator with any N, R or P series filter. Have the test subject put on and adjust the respirator per the instructions provided with the respirator. Have the subject select the size respirator that provides the best fit. The subject may find a mirror useful in the adjustment process. The subject should wear the respirator at least five (5) minutes before starting the test.
- 2) Instruct the subject to put on and position the hood as before and breathe with their mouth slightly open and tongue extended.
- 3) Using the nebulizer labeled BITREX Fit Test Solution, inject the fit test aerosol into the hood. The same number of squeezes is required as was necessary to elicit a response in the threshold sensitivity screening test, i.e., 10, 20 or 30 squeezes.
- 4) To maintain an adequate concentration of aerosol during the test, one half of the initial number of squeezes should be injected again every 30 seconds (i.e., 5, 10, or 15) through out the test.
- 5) After injecting the aerosol initially, ask the test subject to perform the following exercises for 60 seconds each:
 - (a) Normal breathing.
 - (b) Deep breathing.
 - (c) Turning head from side to side, stopping at each end of travel for one or two breaths.
 - (d) Moving head up and down, stopping at each end of travel for one or two breaths.
 - (e) Talking, reciting the alphabet, or reading a prepared text (the Rainbow Passage is recommended, see below).
 - (f) Jogging in place.
 - (g) Normal breathing.
- 6) Instruct the subject to indicate if they detect the bitter taste at any time during the test.
- 7) If the entire test is completed without the subject detecting the bitter taste of the aerosol, the test is passed and the respirator's fit on that individual is judged adequate.
- 8) At any time during the test, if the subject detects the bitter taste of the aerosol the test is stopped at this point. When this occurs, the fit of the respirator on the subject is judged inadequate.
- 9) If the test is failed, before retesting the subject, a 15-minute waiting period must be observed and the taste sensitivity screening test must be performed again. Test again with same Moldex model.
- 10) If the second test fails, repeat tests with another size and/or model Moldex respirator.
- 11) Document results of fit tests for each employee into 1 ml virus culture medium (Opti-MEM with 1% penicillin-streptomycin). Each sample was further incubated at 4°C overnight to reconstitute the virus. The elution culture medium was transferred into triplicate wells of Vero E6 cells seeded in 96-well plates. At 48 hours postinfection, cells were examined to evaluate viral infectivity via observation of cytopathic effects.

