COVID-19 tests are medical procedures which require informed consent from the individual. I have questions regarding the testing procedure being used.

- **Which test is it, manufacturer/model?** As a medical device, Health Canada requires that all tests for COVID-19 include the name and model of the device on the packaging, as well as sterilization methods.

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/testing/test-swabs.html

Labelling
Swabs should be individually packaged and labelled. The application must include the swab label, which must include:

- **the name and model number of the device**
- **the term 'sterile,' along with the sterilization method (EtO = ethylene oxide; R = gamma irradiation), if the swab is intended to be sold in a sterile condition**
- the name and address of the manufacturer
- manufacturing and expiry dates
- **If swabs are not sterile but must be sterilized at the user facility, then the sterilization parameters and method should be clearly described in accompanying instructions for use documentation.**

What is the sterilization method of the test used? There are two main types of sterilization approved in Canada for invasive COVID-19 tests.

- **If sterilized with Ethelyne Oxide, a known carcinogen, and then pressed into the nasopharynx/oropharnyx: are any long term studies available to demonstrate the safety of repeated and long term exposure via COVID-19 testing?**

https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/ethylene-oxide

"The general population may also be exposed [to Ethelyne Oxide] *through tobacco smoke and the use of products that have been sterilized with ethylene oxide, such as* ***medical products****, cosmetics, and beekeeping equipment."*

- **If sterilized via Gamma Radiation, known to damage DNA: are any long term studies available to demonstrate the safety of repeated and long term exposure via COVID-19 testing?**

International Journal of Medical Sciences: Risks of Using Sterilization by Gamma Radiation (C. Randall Harrell, Valentin Djonov, Crissy Fellabaum, Vladislav Volarevic):

https://www.medsci.org/v15p0274.htm

*"**Although gamma radiation is broadly used for the sterilization of medical equipment**, micronized amniotic membrane injectable products and food samples (5-7), **there are many proofs demonstrating deleterious effects of gamma radiation on sterilized products.** "*

*"**Morphological and functional changes, observed in irradiated products, are happening due to the adsorption of energy released during gamma radiation** (7). Several hypotheses attempted to explain the mechanism of gamma rays-induced cell injury (8-12): increased permeability of cellular membrane (8), dysfunction of enzymes (9) and generation of radiotoxins (10). Regardless of the fact that these hypotheses are well documented, it is now widely accepted, **based on the significant number of experimental proofs, that damage of deoxyribonucleic acid (DNA) is mainly responsible for detrimental effects of gamma radiation (11-12). Gamma rays either destruct DNA helix directly, or generate free radicals which disrupt chemical bonds within DNA (11-12)."***

These medical procedures do not have any long term safety data, and are approved only under an interim order by the Health Minister (emergency authorization). Approved medical devices in Canada must be accompanied by a list of known possible risks. The interim order states any COVID-19 test must have a statement of known risks. **What are the known risks of the test that is used?**

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/interim-order-2-import-sale-medical-devices.html

Supplementary information
15 The Minister must publish on a Government of Canada website supplementary information pertaining to the expanded use of a medical device or a COVID-19 medical device, including

(a) a statement of the expanded use;
(b) **a statement of the known and potential benefits and the known and potential risks**; and
(c) any supplement to the directions for use, unless a supplement is not required for the device to be used safely and effectively.

Based on my understanding of the invasive COVID-19 testing devices (swabs, or anything that enters the body or breaks the skin), I do not consent.

There are several non-invasive COVID-19 tests approved by Health Canada which I am willing to take. This is reasonable accommodation. One such test is provided by Ichor Blood Services (1122 40th Av NE, Calgary, AB, T2E 5T8, 1 (844) 424-6728):

https://ichorblood.ca/
https://www.remotecovidtesting.ca/

I've spoken with the company directly and confirmed all details of the saliva based non-invasive test they offer. Results are available within 24-48 hours, and testing is witnessed virtually by the testing centre to confirm authenticity. Results can be obtained from Winnipeg within this time frame. The test is widely used for international travellers; you can purchase the kit, then schedule the test any time, from any location.

Informed consent is required for any medical procedure in Canada; COVID-19 tests which enter the body are medical procedures. There is a reasonable alternative to these invasive medical devices, as such, no invasive procedure is necessary when considering the risks and benefits.