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# Q-POC SARS-CoV-2 Assay (Q27001) Clinical Performance Study Plan

## IRB Approved Informed Consent Form Template

## NCT05614011

## November 9, 2022

# INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

For Adult Participants Only

| | |
|---|---|
| **Sponsor / Study Title:** | **Q-POC SARS-CoV-2 Assay (Q27001) Clinical Performance Study Plan** |
| **Protocol Number:** | **QVTP-39** |
| **Principal Investigator: (Study Doctor)** | **«PiFullName»** |
| **Telephone:** | **«IcfPhoneNumber»** |
| **Address:** | **«PiLocations»** |

This research study is being sponsored by QuantuMDx Group Ltd.

## WHAT IS THE PURPOSE OF THE STUDY?

This is a medical research study. The study will be explained to you by study staff. You may ask any questions. If you have further questions, please contact the study doctor or study staff at the information above.

**Results are for research use only. This is a research study to test a new investigational device. An investigational device is one that is not approved by the United States Food and Drug Administration (FDA). This study device test is not for diagnostic use. If you are symptomatic and wish to be tested for COVID-19, then please consult your primary care physician.**

In this study you will be asked to provide two different nasal swab samples, collected by study staff: one nasal mid-turbinate swab sample for the investigational test one nasopharyngeal swab sample to compare the results of the investigational test using a PCR test approved by the FDA. The nasal mid-turbinate swab sample will be tested by study staff on a research use only Q-POC SARS-CoV-2 Assay. A PCR test is a diagnostic test that determines if you are infected by analyzing a sample to see if it contains genetic material from the virus. A member of the study staff will monitor collections and will assist in completion of study forms.

You will be asked for some facts about yourself. This includes your gender, date of birth, socioeconomic questions, what symptoms of COVID-19 you are experiencing, as well as the date those symptoms started and stopped. These facts will be recorded for the purposes of this study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. The Advarra IRB has reviewed the information in this consent document and has given approval for the study doctor to do the study. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

## PARTICIPANT SELECTION

You are being asked to participate in this study because you are 18 years of age or older and you are exhibiting symptoms consistent with SARS-CoV-2 infection. Approximately 550 people will participate in this study.

## WHAT DOES STUDY PARTICIPATION INVOLVE?

If you choose to participate in this study, you will be asked to complete forms during which we will collect baseline information about your health, disease symptoms, vaccination status, and most recent COVID infection status. This information will be used to see if you are eligible to participate in the study. Prior to any study procedures being performed, you will be asked to sign and date this informed consent form.

If you qualify, you will have the possibility to participate in the study immediately. The study visit will last approximately 10-15 minutes.

During this study the following specimen collection procedures will be performed:

- **Nasal mid-turbinate swab sample**: One nasal mid-turbinate swab sample will be collected by placing a nylon-tipped swab into approximately 1-2 inches deep by the study staff.
- **Nasopharyngeal Swab:** One Nasopharyngeal swab will be collected by placing a nylon-tipped swab into the back of your nose by the study staff.

## ARE THERE ANY RISKS?

**Nasal mid-turbinate swab:** The nasopharyngeal swab may cause pain or discomfort, your eyes may tear up, you might gag and you might have a minor nosebleed.

**Nasopharyngeal Swab:** The nasopharyngeal swab may cause pain, your eyes may tear up, you might gag and you might have a minor nosebleed.

**Exposure to Chemicals:** There is a rare risk of chemical contamination due to the study device application.

**Risk of disclosure:** Your research samples and data will not be labeled with your name or other personal identifiers. All data will be stored in a password-protected, study-specific database and will be labeled with a code number. There will be very limited access to the link between your name or other personal information and the study code. Because this link will exist, there is a risk that your name and medical information may become known in association with this research study.

**UNFORESEEN RISKS**
There may be other risks of study participation that are unknown.

**SHOULD ANY PROBLEM ARISE AFTER THE STUDY**
Should any problems arise after the study, you should contact any of the study staff to notify them so the problem can be documented.

**NEW FINDINGS**
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

**ALTERNATIVE TO PARTICIPATION**
This study is for research purposes only. The only alternative is to not participate in this study.

**BENEFITS**
Since the results of the nasopharyngeal swabs will be used for research only, there is not a benefit for you from providing this specimen. **The COVID-19 test results will be used for research purposes only and not for treatment from your provider.** The results from the study tests will not be shared with you. Information learned from the study may help other people in the future to enable easier specimen collection for COVID-19 detection.

**VOLUNTARY PARTICIPATION / WITHDRAWAL**
Your decision to participate in this study is voluntary. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. If you want to stop being in the study, contact the study doctor.

Your remnant sample will be frozen for future research. It will not include any information that could identify you. If you want your sample disposed of, contact the study doctor.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study
- If it is discovered that you do not meet the study requirements
- If the study is canceled
- For administrative reasons, including the target number of COVID-19 positive participants has entered the study

**WHO PAYS FOR MY RESEARCH RELATED ILLNESS OR INJURY?**
Neither research related illness nor injury are anticipated for this research study. A research-related injury or illness is a direct result of either the study device or a study procedure performed only as a part of this study and that is not part of your standard

clinical medical treatment. Injury or illness related to your underlying medical condition or caused by non-research-related activities (such as treatment generally provided outside of the study) would not be considered research-related.

If you are being treated for a research-related injury or illness, you will not pay for the costs of your appropriate medical or emergency room care provided so long as it is determined that your illness or injury is research-related. There are no plans to pay for losses such as lost wages.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing and dating this consent document.

A new public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a participant participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19. This includes the study diagnostic device ND COVID-19 Ag Test used in this study. Participants using ND COVID-19 Ag Test in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

**COSTS**

There will be no charge to you for your participation in this study. The study-related procedures and study visits will be provided at no charge to you or your insurance company.

**WILL I BE PAID FOR MY PARTICIPATION IN THE STUDY?**

«Compensation»

If eligible to participate in the study, you will be compensated with a $75 stipend.

You will be paid upon completion of all study-related activities, including completion of all associated forms.

**WILL MY CONFIDENTIALITY BE PROTECTED?**

We will do our best to make sure that the personal information collected as part of this study is kept private. However, we cannot guarantee total privacy. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review

Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. A copy of your research consent and authorization forms may be filed in your electronic medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other identifiable personal information will not be used.

Records of your participation in this study will be held confidential except as disclosure is required by law or as described in this informed consent document (under this section or "Authorization to Use and Disclose Protected Health Information"). The study doctor, the sponsor or persons working on behalf of the sponsor, will be able to inspect and copy confidential study-related records which identify you by name. Therefore, absolute confidentiality cannot be guaranteed.

The study staff might use information learned from this study in scientific journal articles or in presentations. None of these data will identify you personally. The data will be coded with a study specific identification number and not your name. Paper copies of study related information will be kept in a locked file cabinet in the study staff office. All electronic data is password protected and does not contain information that identifies you. The study staff will be the only people to have access to personal information.

At the completion of any study participant data will be deleted from the research database. Separately stored, deidentified study data including age, gender, race, weight, and height will be stored indefinitely.

**COMMERCIAL GAIN**

This study investigates how a new investigational study device can be used for specimen collection related to COVID-19 testing. Your information collected during this study may be used for the development of new processes or services for use in clinical trials. The sponsor has no plans to offer you financial compensation or share any profits from the commercialization of any processes or services developed from your information. You will not, however, lose any legal rights to which you are entitled by signing and dating this consent.

**WHOM TO CONTACT ABOUT THIS STUDY**

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study, such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

**Please contact the study doctor at the telephone number listed on the first page of this consent document.**

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00067613.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## CONSENT/ASSENT/PARENTAL PERMISSION

If you sign and date this form below, it means that:

(1) You have taken the time to carefully read and understand the information presented in this informed consent form; you should discuss it with others, and if appropriate seek a second opinion to make an informed decision
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction
(3) You have received and understand all of the information you desire regarding your participation in the research study
(4) You have considered the potential risks, any anticipated benefits, and alternatives (and their relative risks and benefits) of participation
(5) You are voluntarily agreeing to participate in this research study
(6) You understand that by consenting to participate in the research, you are not giving up any of your legal rights (other than the postponement of your access to certain health information as described in this informed consent form)
(7) You understand that you have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study
(8) By signing as the Parent or Legal Guardian you indicate that you have the state and local legal authority to do so for the minor being tested

We will give you a copy of this signed and dated consent form.

## CONSENT BY THE ADULT STUDY PARTICIPANT:

_____

Printed Name of Adult Study Participant

_____

Signature of Adult Study Participant

_____ _____

Date Age

## AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Year of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your study doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of the sponsor QuantuMDx Group Ltd.
- Representatives of the study contract research organization EDP Biotech Corporation.
- Representatives of Advarra (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the study, including for instance:

- To see if the study device works and is safe.
- To compare the study device to other devices.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on

the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

**STATEMENT OF AUTHORIZATION**

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Adult Study Participant

_____

Signature of Adult Study Participant

_____

Date