Title of the study:

Brussels Airport Pilot study: “Comparison of the standard COVID-19 test with a rapid test on nasopharyngeal swabs and breath samples”

Sponsor of the study:

miDIAGNOSTICS n.v.
Ubicenter - Philipssite 5/PB 11 - 3001 Leuven – Belgium

Research institute and principal investigator

Dr. Dirk Bernard
EUROFINS Labo Van Poucke BV
Engelse Weg 7 – 8500 Kortrijk - Belgium

I Necessary info to take your decision (4 pages)

Introduction

You are invited to participate in a study where an additional nasopharyngeal sample will be taken from you to compare a new diagnostic method with the current standard diagnostic methods.

Before you agree to participate, we ask you to familiarize yourself of what this study will entail in terms of organisation, so you can take a properly informed decision, which is called an “informed consent”.

We ask you to carefully read the following pages with information about the study. If you have questions, you can always contact the doctor-researcher or his representative.

This document consists of 3 parts: (I) essential information that is required to take your decision, (II) your informed consent and (III) supplemental information where you can find more details about certain aspects of the essential information.

By participating to this study, you should know that:

- This interventional study is set up after evaluation by one ethical committee.
- Your participation is voluntary, there can never be any form of forced participation. To participate, your informed consent is needed. Also after signing this document, you can inform the doctor-researcher that you would like to stop your study participation.
- You will not be charged any costs for the actions performed in view of this study.
- The data collected in view of your participation are confidential. In case of publication of results, anonymity is guaranteed.
- An insurance has been taken in case you would suffer physical damage by participating to this study.
- If you would like to receive additional information, you can contact the doctor-researcher or his team at any time.

Additional information on your “Rights as participant to a clinical study” can be found in Supplement III.

Goals and course of the study

This study is organised to make a comparison between the already existing PCR test for diagnosing a COVID-19 viral infection with our new similar, but more rapid PCR test. The goal of this study is to investigate if the results with the new, more rapid test are sufficient for further development of this new technology. To be able to introduce this new method as supplementary or alternative method to the current methods, the new method should be compared to the current methods. This comparison is what we would like to perform in this study.

You are being asked to take part in this study because you will be tested with the standard diagnostic test at the departure of or return from your flight trip. We now ask you to undergo one additional nasopharngeal sampling. This extra sample will be analysed with our new rapid test.

If you decide to participate, the doctor-researcher/study responsible will ask you some questions to collect all data and information that is required for the study. This data includes your gender and age, as well as the country you are travelling to/returning from. Next, the following is required from you: After you have donated the nasopharyngeal swab for analysis by the standard PCR method, we will take a second nasopharyngeal sample. Both samples will be taken by the standard clinical procedure The result of the standard diagnostic test will be compared with the result of the new rapid test. You will only receive the result of the standard test. We will however not share the results of the new PCR method, since this is still an experimental, and thus non-validated, technique which cannot yet be used as a diagnostic test.

A maximum of 1000 persons will participate in this part of the study. To be able to participate in this study, you need:

- To be an adult and are considered to be able to independently decide on your participation;
- To be willing to adhere to all study requirements.

Description of the risks and advantages

As mentioned above, the applied procedures for diagnosis are compliant with good medical practice. You will undergo the standard clinical protocol with a nasopharyngeal swab, that you will undergo in any case as part of the standard PCR test. The nasopharyngeal swabs will be carefully performed by a qualified person and therefore should not carry any risks for your health. The only foreseeable side effects are temporary inconveniences such as nose bleed, irritation and/or itching of the nasal cavity, sneezing and tearing eyes.

This study will not bring you any personal benefits. You should understand that your participation to this study will allow us to better understand the functioning of the new rapid test method, and consequentially, to make the new rapid test generally available in the future.

You will receive a compensation for your time during the visit (see page 7 for more information).

Withdrawal of your consent

You voluntarily participate to this study and you have the right to withdraw your consent for any reason. You don’t have to give a reason to do so.

If you withdraw your consent, the data that have been generated up until the moment of your withdrawal will remain stored in order to guarantee the validity of the study results. No new data will be provided to the sponsor.

The sponsor/responsible of the study could also decide to stop the study at any point in case the collected results allow to draw the study conclusions earlier than foreseen.

Your participation in the study can also, without your permission, be stopped at any point by the researcher(s), the Ethical Committee or the study sponsor. Potential causes for this decision could be:

- You do not comply to the instructions for participation to the study;
- Any further participation appears to be harmful to you;
- During the study it is concluded that you do not or do no longer fulfil the requirements to participate to the study.

If you participate to this study, we ask you to:

- Fully comply to ensure a correct progress of the study.
- Do not withhold any information on your physical condition or the symptoms you experience.

Biological samples taken during this study

- The study sponsor guarantees that the samples will be used exclusively for the context described in the sections on “Goals and course of the study” and the corresponding supplemental information.
- Samples will be stored during the duration of the study and will be destroyed at the end of the study.

Contact

If you wish to receive additional information, or in cases of problems, or if you are worried, please contact the doctor researcher:

Name: dr. Dirk Bernard
Telephone number: +32 495 24 97 52
Email address: d.bernard@labovanpoucke.eu

If you have questions related to your rights as participant in the study, you can contact the Ethical Committee Research UZ/KU Leuven [ec@uzleuven.be; 016 34 86 00 (week days between 10 and 11 AM)].

Title of the study: Brussels Airport Pilot study

II Informed consent

Participant

- I declare to be informed about the nature, the goal, the duration, the potential advantages and risks of the study and I am aware what is expected of me. I have read and understood the information document and the supplemental information.
- I have had sufficient time to reflect and discuss the study with a person of my choice (e.g. relative).
- I had the opportunity to ask all questions that came to my mind and I have received a clear answer to these questions.
- I understand my participation to this study is voluntary and I am free to stop my participation at any moment without the need to give a reason for this.
- I understand that during my participation to this study data will be collected about me and the doctor-researcher and study sponsor ensure the confidentiality of these data in compliance with the applicable European and Belgian legislation.
- I agree to the processing of my personal data according to the modalities described in the sections on privacy and confidentiality (Supplemental info III).
- **I agree / do not agree (delete what is not applicable)** to the study data collected for the purposes of this study being processed at a later date provided this processing is limited to the context of the present study for a better understanding of the disease and its diagnosis.
- I have received a copy of the information for participants and the informed consent document.

First name, last name, date and signature of the participant:

Doctor-researcher

- I, the undersigned doctor-researcher/qualified representative, declare to have provided the necessary information regarding this study to the study participant in an oral way, as well as by means of the information document.
- In confirm that in no way the participant was pressured to make him/her agree to participate to the study and I am prepared to answer any potential extra questions.
- I confirm to work according to the ethical principles described in the “Helsinki declaration”, the “Good clinical practices” and the Belgian law of May 7th 2004 concerning experiments on a human person.

First name, last name, date and signature of the doctor-researcher / qualified representative:

Title of the study: Brussels Airport Pilot study

III Supplemental information

1: Additional information on the study organisation

This supplement contains a short description of the study.

You are asked to participate to this study because you leave on or return from a flight trip, for which a RT-PCR test for COVID-19 is required.

To compare our new fast PCR method with the already existing methods, we will ask you to undergo one additional nasopharyngeal sampling. The results of this fast PCR will then be compared with the results of the standard diagnostic test

When participating, you will also be asked for your gender and age, and the country you are travelling to/from will be noted.

When can you participate?

- You are adult (18 years or older).
- You are leaving on/returning from a flight trip.
- You don't have any severe COVID-19 symptoms (shortness of breath, breathing problems, pain or pressure in the chest, problems with speaking or moving).

When can't you participate?

- If you do not wish to participate.
- If you are unable to read and understand this information by yourself.

2: Additional information about the risks of participating to this study

During this study you will be asked to donate two nasopharyngeal swabs, taken following the standard procedures. This sampling will be carefully performed by a qualified person and therefore should not carry any risks for your health. The only foreseeable side effects are temporary inconveniences such as nose bleed, irritation and/or itching of the nasal cavity, sneezing and tearing eyes.

3: Additional information on the protection and rights of the participant to a clinical study

Ethical Committee

This study has been evaluated by an independent ethical committee: Ethical Committee Research UZ/KU Leuven has given a positive advice. Ethical committees have the duty to protect individuals participating to clinical studies. They verify that your rights as participant to a study are respected, and whether the study is scientifically and ethically justified.

On these matters, ethical committees give an advice in accordance to the Belgian law of May 7th 2004.

You should by no means consider the positive advice of the Ethical Committee as an urge to participate to this study.

Voluntary participation

Do not hesitate to ask questions you find useful before signing the document. Take the time to talk about it with a confidant if you wish to do so.

You have the right not to participate to this study or to stop this study without having to provide a reason for this decision, even if you previously agreed to participate to this study. Your decision will certainly not affect your relation with the doctor-researcher.

If you agree to participate in this study, you will sign the informed consent form. The doctor-researcher or his representative will also sign this form, hereby confirming he has given you the necessary information about this study. You will receive the copy that is intended for you.

Costs related to your participation

Participants will receive a compensation by means of a gift card of 25 EUR. The gift card can be used in Brussels Airport. Your participation will not bring any additional costs for you.

Privacy

Your consent to participate to this study means you agree to have your data processed in view of the scientific research described in this information document and that these data are transferred to the parties involved in this study.

We process the following data from you in this research study:

- Demographic data: age and gender
- To/from which country you travel
- Results of all tests

The following parties can have access to your data:

- Researchers of miDiagnostics n.v. have access to the coded data in order to execute the scientific research.
- Researchers and the doctor-researcher of Eurofins and Ecolog International have access to the data to provide you with the result of your standard PCR test, to execute additional scientific research.

Confidentiality guarantee

Your participation in the study means that you agree to the investigator collecting data about you and to the study sponsor using these data for research purposes and in connection with scientific and medical publications.

Your data will be processed according to the European General Data Protection Regulation (GDPR) and with the Belgian legislation on the protection of natural persons with regards to the processing of personal data. miDiagnostics n.v. is the study sponsor and data controller and engages Eurofins and Ecolog International as data processor for a number of processing activities. Eurofins and Ecolog International remain the data controllers for all data processing activities related to your personal data.

You are entitled to ask the investigator what data are being collected about you and what is their use in connection with the study. This data concerns your current clinical situation but also some of your background, the results of examinations carried out within the context of care of your health in accordance with the current standards and obviously the results of examinations required by the protocol. You have the right to inspect these data and correct them if they are incorrect.[1]

The doctor-researcher of Eurofins is obliged to treat the collected data as confidential information. This means that he commits to never reveal your identity in the context of a publication or conference and that he will code your data by replacing your identity with an identification code needed for the scientific research. The doctor-researcher is also responsible for storing the signed informed consent documents.

The personal data transmitted will not contain any combination of elements that might allow you to be identified.[2]

For the study data manager designated by the sponsor, the data transmitted will not allow you to be identified. The latter is responsible for collecting the data gathered by all investigators taking part in the study, processing them and protecting them in accordance with the requirements of the Belgian law on the protection of privacy.

In order to verify the quality of scientific research, your medical records can be examined by persons bound to professional secrecy, such as representatives of the ethical committees, the sponsor of the scientific research, regulatory bodies, or an external audit bureau. This can only happen under strict circumstances under the responsibility of the doctor-researcher and under his supervision (or that of one of his or her research staff members).

The (encoded) study data will be able to be sent to Belgian or other regulatory authorities, to the relevant ethics committees, to other doctors and/or to organisations working in collaboration with the sponsor.

They will also be able to be sent to other sites of the sponsor in Belgium and in other countries where the standards in terms of the protection of personal data may be different or less stringent.[3] As explained above, the transmitted data are encoded.

Your consent to take part in this study therefore also implies your consent to the use of your encoded medical data for the purposes described in this information form and to their transmission to the aforementioned people and authorities.

The sponsor will use the data collected within the context of the study in which you are taking part, but would also like to be able to use them in connection with other research concerning the same disease indications as in this study (e.g. respiratory diseases). Any use of your data outside the context described in this document is only possible with the approval of the ethics committee.

If you have questions about how miDiagnostics n.v. uses your data, you are referred to miDiagnostics n.v., Ubicenter - Philipssite 5/PB 11 - 3001 Leuven - Belgium. If you have questions on the study, you can contact the doctor-researcher and his or her team.

[1] These rights are guaranteed by the European Data Protection Regulation (GDPR), by the Belgian legislation on the protection of natural persons with regard to the processing of personal data and by the Law of 22 August 2002 on patient rights.
[2] The database containing the results of the study will therefore not contain any combination of elements such as your initials, your gender and your full date of birth (dd/mm/yyyy).
[3] The sponsor then undertakes to respect the constraints of the European General Data Protection Regulation (GDPR) and the Belgian legislation on the protection of natural persons with regard to the processing of personal data.

Finally you also have the right to press charges on how your data are being processed with the Belgian regulatory body responsible for governing the law on data protection:

Gegevensbeschermingsautoriteit (GBA)
Drukpersstraat 35, 1000 Brussel
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be

If you decide to withdraw your consent to use your coded medical data in view of the scientific research, no additional data will be transferred or used. However, the data that was transferred and used prior to that moment can remain stored and can be used in order to guarantee the validity of the research.

Confidentiality guarantee sampling

The biological samples taken from you, will be analysed within the scope of the study. The remainder of your biological samples will be destroyed after the study ends.

For the samples, the same coding principles as for your medical data will be used. The samples that are provided to the sponsor will only contain the identification code related to the study.

The biological material obtained is considered a “gift” and you need to be aware that you will not receive any financial advantage (i.e. royalties) related to the development of new therapies based on the use of the by you donated biological material that may have commercial value.

The doctor-researcher is responsible to guarantee the traceability of your biological samples.

When you withdraw your consent, you have the right to have your collected biological samples destroyed or returned, should they still be relevant in the context of your treatment. However, samples which have already been used in the study at the time of withdrawal of your consent, cannot be destroyed retroactively. Data obtained from the analysis of the respective samples will remain the property of the sponsor in order to guarantee the validity of the research.

Insurance

Any participation in a clinical study involves a risk, however small it is. Even if there is no fault, the sponsor accepts responsibility for damage caused to the participant (or in the event of death, his/her dependants) and directly or indirectly linked to his/her participation in the study. The sponsor has taken out insurance for this responsibility.[4]

If the investigator believes that a link with the study is possible (the insurance does not cover the natural progression of your disease or the known side effects of your normal treatment), he/she will inform the study sponsor, which will initiate the declaration procedure to the insurance company. The latter will appoint an expert - if it considers it necessary - to assess whether there is a link between your new health problems and the study.

[4] In accordance with Article 29 of the Belgian Law related to experiments on humans (7 May 2004)

In the event of disagreement either with the investigator or with the expert appointed by the insurance company and also whenever you feel it is appropriate, you or - in case of death - your dependants may bring proceedings against the insurer directly in Belgium

Chubb European Group SE
Terhulpsesteenweg 166, 1170 Brussel
Policy number : BELSCA06987

The law provides that the insurer may be summoned to appear either before the judge of the location where the event giving rise to the damage occurred, or before the judge of your domicile, or before the judge of the insurer’s registered offices.