

Patient Information Handout

Comparison of Different Methods for Detecting Diseases of the Skin, Nails or Hair Caused by Fungi

Dear Patient,

Your doctor would like to ask that you participate in a study that aims to develop new concepts for detecting diseases of the skin, nails and hair caused by fungi. This patient information handout is intended to provide additional information on this study and is a tool that can help you decide on your participation. Please carefully read through this patient information and discuss any remaining questions with your doctor before making your decision.

BACKGROUND AND PURPOSE OF STUDY

Early and correct detection of fungal infections is important for fast treatment and healing. We are asking patients to participate in a short study to learn more about care and treatment of fungal infections.

Traditionally, the diagnosis of a superficial fungal infection is often quite involved and requires a certain amount of time. Your sample is microscopically analysed, and an attempt will be made to cultivate the relevant pathogen in order to identify it based on its appearance and growth characteristics. As fungi are often very slow growing, it will often take a few weeks before a conclusive result is available.

By contrast, the new molecular diagnostic methods used in this study can detect pathogens in a few hours based on specific gene sections of the relevant type of fungus. However, these methods are not currently used in routine diagnostics.

This study aims to investigate whether molecular biological methods are also suitable for everyday clinical practice and whether they could present an alternative or addition to the detection of fungi by culture method.

HOW YOU WILL BE PARTICIPATING IN THIS STUDY

Test

For the study you will be asked to provide a skin, hair, or nail sample. If your doctor decides you may need treatment, your doctor will collect a second skin, hair, or nail sample at a later date. This second sample will be collected from you to see how treatment has worked.

Survey

You will also be asked to fill out the short, attached survey so that we can better understand your experiences (if any) with fungal infections. In this survey we will ask about history with fungal infections and questions about possible sources of exposure. The surveys are optional but will help us to evaluate these methods for the benefit of all Ontarians with superficial fungal infections.

For each survey you complete, you will receive a small gift from Alpha Laboratories, via mail or email, as a token of appreciation.

BENEFITS OF PARTICIPATING IN THE STUDY

The results of the molecular diagnostic pathogen detection test will be taken into consideration in the diagnosis of your disease and will be available to your treating doctor for diagnosis in addition to the results of the routine diagnostics. It is expected that this new method will enable faster and more sensitive identification of pathogens, with an equivalent or better quality of the result, so that pathogen-specific and more promising treatment can start earlier. In addition, your participation in this study will enable faster detection of fungal infections in the future.

RISKS OF PARTICIPATING IN THE STUDY

Your participation in this study is not associated with any identifiable risk. Your sample will also be examined in accordance with state-of-the-art techniques and these results will be used as the basis for your further treatment, so the additional examination cannot have any negative influence on your medical care. The test is already approved for use in Health Canada and is in use in 15 other countries.

PRIVACY AND CONFIDENTIALITY

All of your answers to the survey will be strictly anonymous. The records about you or relating to your test results and care will be kept strictly confidential. No information will be released or printed that would disclose your identity without your permission, unless required by law.

As a Health Information Custodian, Alpha will abide by Privacy Requirements set out by the Personal Health Information Protection Act (PHIPA). Your responses will be confidential, and all data will be stored in a secure system. Alpha will take reasonable steps to anonymize and de-identify the data in question.

PARTICIPATION AND WITHDRAWAL

Participation in any research study is voluntary. If you decide to participate in this study you can change your mind at any time without giving a reason, and you may withdraw from the study at any time. If you choose to withdraw from the study at any point, the study data collected up to the point of withdrawal will be used for analysis. No further information will be collected from you.

This study is being conducted in cooperation with EUROIMMUN. If you have any questions regarding the study, please contact the doctor who provided the information or euroarray@alphalabs.ca or contact (416) 449-2166 ext 1358.

If, after clarifying any questions and reading this information, you are prepared to participate in the study, we ask that you please sign the declaration of consent for the study.

Wishing you good health,

Idelta Coelho,
Vice-President, Alpha Laboratories

DECLARATION OF CONSENT TO PARTICIPATE IN A RESEARCH STUDY

I acknowledge that the study described above has been explained to me and that any questions that I have asked have been answered to my satisfaction.

I understand:

- That the purpose of this project is to better understand how to use fungal tests to improve patient care
- That my participation in this project is voluntary
- I may choose to withdraw from this project and revoke my consent at any time, without penalty
- I may choose to decline answering questions I feel uncomfortable with
- I have read and understood the explanation provided to me and have had all my questions answered to my satisfaction
- I have been given a copy of this consent form

I have read and understood the above, and I hereby consent to participate.

Participant's Name (Printed)

Participant's Signature

Date

Email Address: _____

Signature of the Doctor