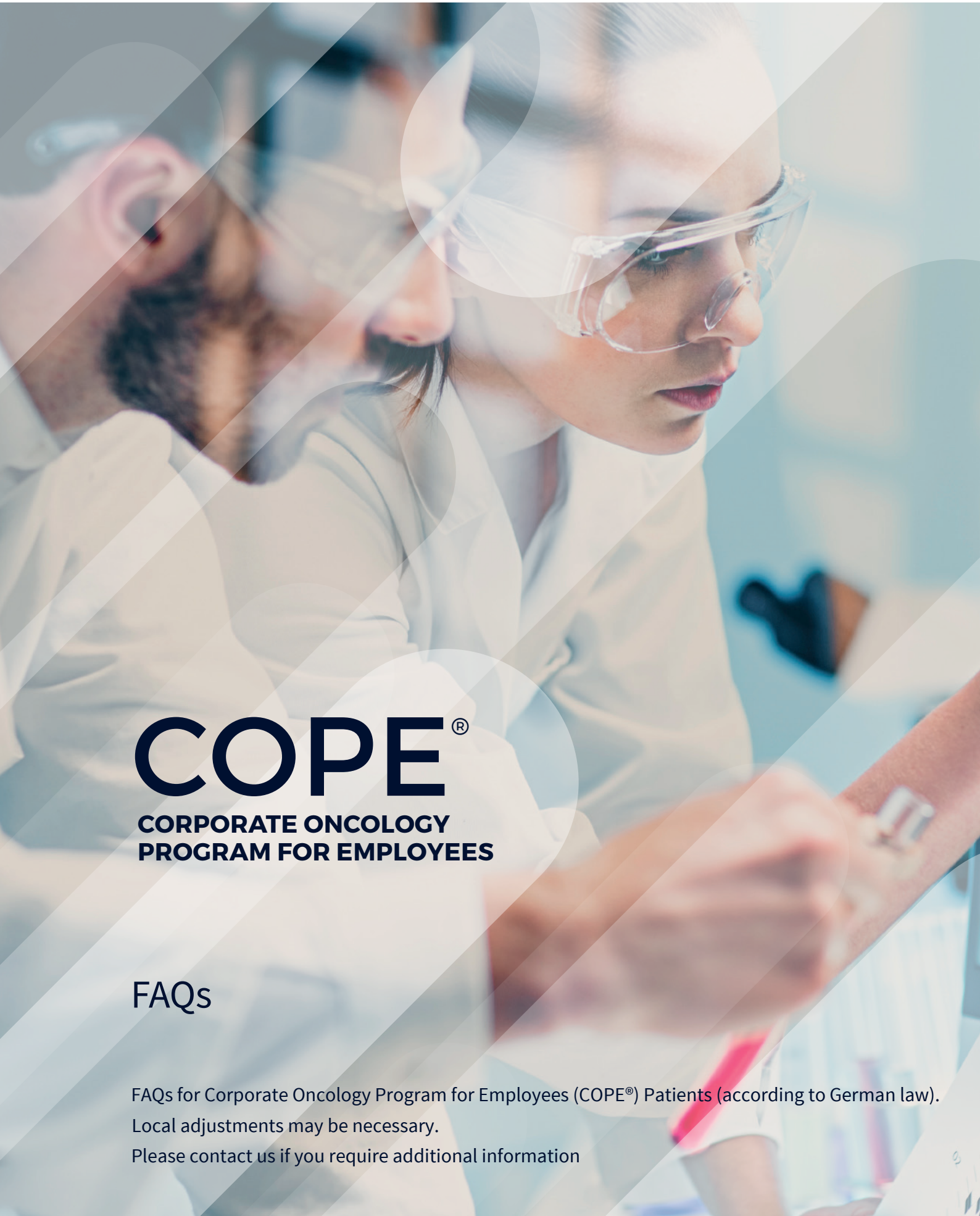
INSTITUTE OF
IMMUNOLOGY AND GENETICS
HUMAN GENETICS I PATHOLOGY

MOLECULAR HEALTH™



COPE®

CORPORATE ONCOLOGY PROGRAM FOR EMPLOYEES

FAQs

FAQs for Corporate Oncology Program for Employees (COPE®) Patients (according to German law).
Local adjustments may be necessary.
Please contact us if you require additional information

CONTENT

1. WHAT IS THE CORPORATE ONCOLOGY PROGRAM FOR EMPLOYEES (COPE®)?*

COPE is part of the corporate health program that can allow employees with cancer to have access to precision medicine (customized treatment). The goal of precision medicine is to utilize novel diagnostic methods to come to a measurably more exact understanding of the unique medical status of an individual and to use this understanding to improve the clinical outcome for each patient. COPE was developed by Molecular Health and is provided by the Institute of Immunology and Genetics (IIG) in Kaiserslautern, Germany. The COPE program covers all the costs of the genetic analysis. The results of this analysis can provide treating physicians with important information that can allow them to make better-informed, more precise treatment decisions.

In COPE, genome sequencing can be performed either solely on a tumor sample or in combination with a healthy tissue sample. MH Guide certified physicians at the IIG then use Molecular Health Guide® (MH Guide), a specialized clinical decision support software, to identify significant genetic changes in the patient's tumor. These genetic changes are linked by MH Guide to biomedical reference information, aiding the physicians to view the patient's cancer in the context of scientific research and to select potentially safer and more effective treatment recommendations. Two options are available for genome sequencing: (i) targeted sequencing of a panel of approximately 600 genes, specifically selected based on their therapeutic relevance in cancer, or (ii) whole exome sequencing, comprising the complete set of approximately 20,000 human genes.

2. WHAT IS THE INSTITUTE OF IMMUNOLOGY AND GENETICS (IIG)?

Founded in 1997, the IIG in Kaiserslautern, Germany, focuses on the highly specialized areas of human genetic, immunological, and microbiological diagnostics.

IIG's clients include universities, specialized medical centers, clinics, research institutes, research pharma companies, and stem-cell donor organizations, as well as courts of law in the context of forensic tests.

The institute belongs to the non-profit organization Eurotransplant, is registered at the NMDP (US National Marrow Donor Program), and approved for diagnostic procedures related to stem cell transplantations.

3. WHAT IS MOLECULAR HEALTH (MH)?*

MH develops software solutions for clinical decision support. The company was founded in 2004 when it became clear that modern healthcare would develop towards a personalized approach to precision medicine thanks to genome sequencing.

MH captures, integrates, and links the most relevant scientific and medical knowledge available in a quality-controlled database.

Molecular Health Guide® (MH Guide) is an intuitive software application that brings the biomedical reference knowledge of the MH database to MH Guide certified physicians in a clear and actionable form, aiding them to incorporate precision medicine into their routine clinical practice. MH Guide certified physicians can use MH Guide to analyze individual patients' molecular and clinical data and compare them to available disease and treatment knowledge, leading to potentially safer and more effective treatment decisions.

The company is financed by Dievini Hopp BioTech, an investment vehicle of former SAP CEO and founder Dietmar Hopp.

4. WHAT IS MOLECULAR HEALTH GUIDE® (MH GUIDE) AND HOW DOES IT WORK?*

MH Guide is a clinical decision support software developed by Molecular Health for use in precision cancer care. Each patient's tumor cells contain many genetic alterations, making them different from healthy cells but also from another patient's tumor cells. Some of these alterations can affect treatment efficacy and safety, and can serve as a measurable parameter of therapeutic response or drug toxicity (biomarker).

MH Guide assists specially trained physicians (certified physicians) in identifying genetic variant data from a patient's tumor. Based on the user-defined list of reportable variants MH Guide provides a summary of potentially effective medications, potentially ineffective medications, and medications that may pose a higher risk of adverse reactions. Information about relevant variants that may indicate an increased risk of cancer progression is also provided to the MH Guide certified physician. All data collated in the summary are generated from an interactive database of curated, peer-reviewed and published evidence.

MH Guide enables the MH Guide certified physician to manage their workflow from processing data in the bioinformatics pipeline to the generation of a customizable clinical report.

Further questions on whether an MH Guide analysis suits your particular situation should be discussed with your treating physician.

5. WHAT TYPES OF CANCER CAN BE ANALYZED BY MOLECULAR HEALTH GUIDE® (MH GUIDE)?

MH Guide can analyze any type of solid tumor (i.e., no forms of leukemia).

6. WHAT BENEFITS DOES THE PROGRAM OFFER, AND WHAT CAN YOU EXPECT WHEN YOU TAKE PART IN COPE® (CORPORATE ONCOLOGY PROGRAM FOR EMPLOYEES)?

Taking part in COPE and thus allowing Molecular Health Guide® (MH Guide) to perform an analysis allows employees who have cancer to receive access to one of the most innovative technologies and the newest medical insights in the field of oncological molecular diagnostics.

To take part in COPE, you have to meet two conditions:

1) There must be documentation confirming that your employer will assume the cost of the procedure.

2) The treating physician must review your specific case and give permission for the analysis to take place.

A statement confirming financial coverage alone is not enough to take part in COPE.

In addition to consenting to an analysis, the treating physician is also the one who decides the extent to which the results of the analysis will be – and even can be – taken into account in the treatment strategy.

The treating physician will have to review the options presented by MH Guide when it comes to the patient's specific clinical situation. These options can include selecting or administering certain medications, prescribing specific medications, the availability of medication within or outside of the context of clinical trials, and determining what health insurance will cover.

The MH Guide software makes it possible to compare the global body of medical knowledge available while taking into account to the individual genomic constellations of individual patients and their clinical information.

The objective of MH Guide is to identify potentially beneficial therapeutic options for the treating physician to administer to an individual patient. MH Guide deliberately does not in any way select or, by extension, restrict the analytical findings in terms of ruling out factors in applying the treatment results. This selection must be made by the treating physician.

Consequently, a deliberate choice was made not to withhold options in the findings which could potentially become relevant in a patient's treatment at a later point in time. Specifically, this mainly refers to comparing active substances at varying stages of market approval, off-label use, and other options which are not discussed in clinically reviewed guidelines. This situation applies mostly to rare forms of cancer, cases where there are extensive metastases, or highly advanced cases in which previous therapeutic approaches had little or no effect and/or the clinical guidelines have been exhausted.

MH Guide is applied at a far earlier point in the course of the disease and can offer patients critical benefits even at an early phase of treatment.

In Germany as well as in most other countries around the world, there are guideline therapies for well-researched forms of cancer. These guidelines have been extensively reviewed and evaluated. Patients who are already undergoing or are about to undergo guideline therapy can benefit from MH Guide as well.

Under guideline therapy, there is often a certain amount of leeway in drug treatment when it comes to the use of varying active ingredients or combinations of active ingredients. This is where MH Guide is beneficial. Every analysis that is conducted is an ongoing contribution to the database and the state of knowledge for future patients and another step forward in precision medicine. Beyond that, however, MH Guide can provide additional confirmation about an intended therapeutic approach or give the treating physician critical information which can help prevent potential side effects, toxicity or resistance among the various treatment options of guideline therapies. MH Guide can also indicate which approach to treatment is potentially effective for the patient.

7. WHAT IS THE PROCEDURE FOR THE APPLICATION OF MOLECULAR HEALTH GUIDE® (MH GUIDE)?

MH Guide can be applied either solely on a tumor sample or in combination with a healthy tissue sample. In the genome sequencing laboratory, DNA is extracted from the sample(s) and sequenced. The DNA sequence data are sent to Molecular Health and processed with the MH Guide software by a specially trained physician. The customized report from that physician is then transferred to the treating physician to aid him or her in choosing a potentially suitable treatment. No results are sent to your employer.

8. WHAT IS THE TURN-AROUND TIME?

The turn-around time of the complete service (genome sequencing, data processing, medical reporting) is measured from the moment your sample arrives at the IIG to the time a medical report is provided to your treating physician. This processing period is for both, gene-panel sequencing (consisting of about 600 genes) and whole exome sequencing (approximately 20,000 genes) is approximately 4 weeks.

9. WHAT KIND OF INFORMATION DOES THE GENETIC ANALYSIS YIELD?*

Molecular Health Guide® (MH Guide) provides insights about the presence or absence of specific genetic changes (mutations) in the tumor or control sample (healthy tissue) of a patient. In addition, potentially relevant clinical and scientific research information and information about the detection quality are provided for consideration by medical professionals.

The identified genetic variant data do not always deliver non-ambiguous, clinically actionable results, as the genetic alterations cannot always be directly linked to a potentially effective treatment option. This may occur if there is not yet sufficient clinical evidence available for a genetic alteration, or if the detection quality is insufficient, due to quality issues with the samples.

In general, inspection genetic variant data from a patient's tumor has been proven to be a valuable method to better understand an individual cancer patient's condition and to improve the precision of treatment decisions by MH Guide certified physicians and treating physicians. MH Guide provides biomedical reference knowledge of great depth and high quality so that MH Guide certified physicians have a very good evidence base for the clinical interpretation of genetic alterations in cancer patients.

10. HOW ARE MOLECULAR HEALTH (MH) AND MOLECULAR HEALTH GUIDE® (MH GUIDE) VALIDATED AND CERTIFIED?

MH has been audited and certified according to ISO 13485 for the design, development, and manufacture of software systems used for the integrated analysis of clinical and genomic patient data to support treatment decisions and provision of related services (Certificate no: MD 609736). Moreover, MH is accredited according to CLIA/CAP (Clinical Laboratory Improvement Amendments/College of American Pathologists). MH Guide software is registered as an in vitro diagnostic medical device (IVD) in Europe, and has been validated with synthetic and clinical data.

11. HOW IS THE INSTITUTE OF IMMUNOLOGY AND GENETICS VALIDATED AND CERTIFIED?

Amongst other accreditations, the Institute of Immunology and Genetics (IIG), Kaiserslautern, Germany, has been audited and accredited in compliance with DIN EN ISO 15189 for molecular human genetics.

12. WHAT SORT OF INFORMATION IS DERIVED FROM GENETIC DATA?*

Molecular Health Guide® (MH Guide) processes genetic variant data, which are then used to search for matching biomedical data relevant for the treatment of cancer. Genetic information on an inherited predisposition towards certain illnesses is not part of the analysis.

13. WHAT ARE INCIDENTAL FINDINGS AND HOW ARE THEY DEALT WITH?*

In the course of processing genetic data with, Molecular Health Guide® (MH Guide) provides results for genetic alterations which do not relate to the disease in question, but could have medical implications for you or your family. These results are known as incidental findings.

The MH Guide certified physician will not actively search for such information. However, if they come across results which indicate a preventable or curable disease, this information can be forwarded to a genetic counselor if you wish.

Any incidental findings which relate to inherited health conditions and not to your cancer can be outlined to you in the consultation session. You can indicate in the consent form whether you would like to hear about such results.

14. WHAT DO MOLECULAR HEALTH (MH) AND THE INSTITUTE OF IMMUNOLOGY AND GENETICS (IIG) USE THE TISSUE SAMPLE FOR?

MH and the IIG use your sample for your genetic analysis. The sample may also be used for quality control purposes, if you have given consent for this.

15. THE RIGHT TO WITHDRAW CONSENT AND TO REMAIN UNINFORMED

You have the right to refuse genetic analysis from the outset. Once genetic analysis has begun, you still have the right to remain uninformed about some or all of the results, or even to have all of the related information destroyed. You can contact your physician to withdraw your consent to the analysis at any time, verbally (by telephone) or in writing, and you do not need to provide any reasons. You have the right to not know the results (the right to remain uninformed), to stop the ongoing examination process at any time up until the results are communicated to you, and to demand the destruction of materials as well as any results that are have already been obtained at that time. If you do so, be aware that subsequent inquiries about the findings cannot be answered.

16. DO PATIENTS HAVE TO UNDERGO A MEDICAL PROCEDURE TO PROVIDE A TISSUE SAMPLE?

When the Molecular Health Guide® (MH Guide) service is ordered, histological and other routine diagnostic information about your disease should already be available. For most patients, a sufficient tumor sample has usually already been taken and stored, and it is thus available without any further medical intervention for the MH Guide analysis. Should further tissue or blood samples be required for the analysis, your physician will speak to you about it and inform you of any possible related health risks.

17. HOW DOES MOLECULAR HEALTH (MH) ENSURE DATA PROTECTION AND SECURITY?*

Molecular Health Guide® (MH Guide) de-identifies the information you provide for the analysis to protect your data. This means that your name and other identifying features are replaced by a code (a combination of letters and numbers) to make sure a third party cannot identify you.

MH has no access to patients' names and addresses. MH Guide and its IT infrastructure are set up to process, transfer, and store patient data using state-of-the-art technology in compliance with data-protection and gene-diagnostics laws:

- Only de-identified genetic and clinical data are transferred and stored for MH Guide analysis.
- Data for MH Guide analysis are transferred in encrypted format. Analysis results are transferred to the physician using secure access via a Virtual Private Network (VPN).
- Data for the analysis are processed and stored in a certified computing center.
- Only specially trained MH staff have access to MH Guide IT infrastructure.

The MH Guide certified physician who prepares the customized report for your treating physician is the responsible medical specialist as defined by the German Gene Diagnostic Act (GenDG).

Article 12 of this law governs the secure handling of patient data and the retention and destruction of genetic samples and of the results of genetic examinations.

If you wish, the physician will arrange to have all the incoming data and all the generated data destroyed. You will be asked about this in the informed consent form. If you do not request destruction of your data, it will be stored by MH for a minimum of seven years.

On the informed consent form, you may agree to have the de-identified data or results regarding your illness used for research purposes; they may also be used for the purposes of quality assurance of medical devices or in vitro diagnostic medical devices (IVD) and be published in scientific journals.

18. ARE THERE ANY RISKS ASSOCIATED WITH GENETIC DATA?

Genetic data can contain information on inherited predisposition to illnesses. This can also affect your family members and confront you with new situations.

There is also a slight possibility that a patient could be re-identified on the basis of their genetic data. This could only happen in the unlikely scenario that a patient had previously published their genetic information (for example, for genealogy purposes) and that an unforeseen breach of data security occurred at Molecular Health (MH). The security measures implemented by MH to protect data privacy are designed to make such a breach of security impossible. Any misuse of patient data would be punishable by law.

19. WHAT ABOUT MEDICAL CONFIDENTIALITY?

Both the physician who is certified in using Molecular Health Guide® and the treating physician are bound by medical confidentiality, although they may communicate with each other. This is necessary so that they can exchange information on the indication and stage of the illness, on co-medication, and any other clinical information necessary for an optimal treatment decision. They may also discuss a patient's anonymized data with Molecular Health.

20. DOCUMENTATION OF INFORMED CONSENT BEFORE THE GENETIC ANALYSIS

According to the law, you must give informed consent to a procedure before it may be carried out. This ensures that you are given sufficient information about a procedure and that you understood what will happen. By signing the informed consent form, you confirm this and agree to have the genetic analysis conducted. A record of the content of your informed consent is kept by the IIG.

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Institute of Immunology und Genetics
Pfaffplatz 10
67655 Kaiserslautern
Germany
customercare@cope-iig.com

MHL-BRO-2