UniversitätsSpital Zürich
Institute for Pathology and Molecular Pathology
Schmelzbergstrasse 12, 8091 Zurich, Switzerland

FOUNDATIONONE®CDx

Order Form

1. Ordering of the FoundationOne®CDx Service

The FoundationOne®CDx Service comprises the genetic analysis of tumour tissue and the compilation of a comprehensive report on any mutations found in the genes listed in the guidance notes "Technical Information and Test Overview".

Please send the completed form by fax (+41 (44) 255 4552) or e-mail (fmi.pathologie@usz.ch) and the original separately by post to the University Hospital Zurich, Institute for Pathology and Molecular Pathology, Schmelzbergstrasse 12, CH-8091 Zurich.

The University Hospital Zurich will then contact the referring pathologist about sending the block of tumour tissue.

The FoundationOne®CDx Service is performed at the University Hospital in Zurich and Foundation Medicine, Inc. in Cambridge, MA, USA.

Customer Care Service:

University Hospital Zurich, Institute for Pathology and Molecular Pathology
Tel.: +41 (44) 255 2511 E-mail: fmi.pathologie@usz.ch

The patient must address the treating physician directly if he/she has any questions or requires information regarding the test results.

2. Requester (treating doctor)

Last name, First name	
Hospital/Practice/Clinic	
Address	
Tel./E-mail	

Date:_____ Signature of treating doctor: : _____

3. Referring Pathology unit, if not Zurich University Hospital

Last name, First name of the primary assessor	
Hospital/Institute	
Address	
Phone/email	

4. Patient data and billing information

Gender	Male ☐ Female ☐
Last name, first name	
Date of birth	
Address	

Invoice to be sent to: Patient ☐ Referring doctor ☐ Other _____

Copy of the FoundationOne®CDx report to be sent to: _____

5. Specimen details

Specimen ID	**Diagnosis**
Specimen site (organ)	**Disease stage**
Date of biopsy	**International classification (ICD-O code)**
Specimen type, fixation	**Has the patient received a transplant?** No ☐ Yes ☐ Please specify

Notes/queries:

6. Contractual terms and information

Please read through the following instructions carefully before ordering our product:

The FoundationOne®CDx Service: The FoundationOne®CDx service was developed and its performance characteristics were defined by Foundation Medicine, Inc. (Foundation Medicine). The FoundationOne®CDx service can be used for clinical purposes and is not intended solely for research purposes. The clinical reference laboratory of Foundation Medicine has received certification with qualification for performing highly complex clinical investigations in accordance with the 1998 Clinical Laboratory Improvement Amendments (CLIA). The FoundationOne®CDx service has been approved by the United States Food and Drug Administration (FDA).

Diagnostic significance: The FoundationOne®CDx service detects changes in genes or sections of genes (biomarkers) associated with cancer. Insofar as it is clinically relevant, the report will also refer in some cases to selected biomarkers that tested negative.

Qualified presentation of the results (equivocal and subclonal): If a change is described as "Amplification – equivocal", this means that the FoundationOne®CDx service has yielded an indication, but no clear evidence, that the number of copies of a gene exceeds the limit for identifying an amplification. The limit used in the FoundationOne®CDx service for identifying a copy-number amplification is five (5) for ERBB2 and six (6) for all other genes. Conversely, a change described as "Loss – equivocal" means that the FoundationOne®CDx service has yielded an indication, but no clear evidence, of the homozygous deletion of the gene in question. A change described as "subclonal" means that the methods of the FoundationOne®CDx service found a change present in < 10 % of the tumour DNA analysed.

The report contains analyses of peer-reviewed studies and other publicly available information compiled by Foundation Medicine. This summary and the information it contains may describe molecular changes (or the absence of a change) in the context of one or more active substances with a potential clinical benefit (or the absence of a potential clinical benefit), including active substance candidates that are currently undergoing clinical research.

NOTE: If a change in a biomarker is detected, this does not necessarily indicate pharmacological efficacy (or the absence thereof) of an active substance or therapy regime. Conversely, if no biomarker change is detected, this does not necessarily indicate the absence of pharmacological efficacy (or the presence thereof) of an active substance or therapy regime.

The list of changes and active substances is not ordered/weighted: In the report, neither the changes to any biomarker nor active substances associated with a potential clinical benefit (or the absence of thereof) are sorted or weighted according to possible or expected efficacy.

No evidence level is provided: Active substances with a potential clinical benefit (or the absence thereof) are not evaluated according to the source or the strength of the published evidence.

A clinical benefit is not guaranteed: The report makes no promises and provides no guarantees that a given active substance will be effective in treatment the patient's disease or that a substance which does not show a potential clinical benefit will indeed have no clinical benefit.

Reimbursement is not guaranteed: Zurich University Hospital, Foundation Medicine and Roche make no promises and provide no guarantees that a healthcare service provider, a health insurer or a third party, regardless of whether private or state-owned, will reimburse the costs of the FoundationOne®CDx service to the patient.

Therapy decisions are the physician's responsibility: The active substances included in the report may not be suitable for some patients. The selection of one, all or none of the active substances with (or without) a potential clinical benefit is at the full discretion and responsibility of the treating physician. In addition, the information contained in this report must be considered in conjunction with all other relevant information in relation to the respective patient, before the treating physician recommends a certain treatment.

Decisions concerning the medical care and treatment of a patient must be based on an independent medical assessment by the treating physician, taking into account all the available information on the patient's condition. This information includes, for example, the patient's medical history, their family history, physical examinations, data from other diagnostic investigations, and the patient's preferences, in accordance with the local standard of care in each case. The treating physician's decision should not be based solely on individual test results – such as from this service – or the information contained in the report.

Certain specimens or variant characteristics may lead to reduced sensitivity. These include: subclonal changes in heterogeneous specimens, poor specimen quality or specimens with homozygous gene loss of < 3 exons and deletions and insertions > 40 bp, or in repetitive/highly homologous sequences. The FoundationOne® service is performed using DNA harvested from tumours. Changes in the germ line may therefore not be recognised. The following targets typically have a lower coverage, which leads to reduced sensitivity: *SDHD exon 6 and TP53 exon 1.*

Liability waiver: Where legally permissible, any liability on the part of University Hospital Zurich is excluded.

Applicable law and place of jurisdiction: This order is subject exclusively to Swiss law. The place of jurisdiction is Zurich.

7. Patient consent for order

I hereby consent to my treating physician forwarding my patient data and biological tumour tissue to the University Hospital Zurich, Institute for Pathology and Molecular Pathology, Schmelzbergstrasse 12, CH-8091 Zurich, Switzerland, for the purpose of performing and billing the treatment contract.

The University Hospital Zurich, Institute for Pathology and Molecular Pathology, will conduct the genome sequencing and forward the sequencing data together with the required patient information to the laboratory of Foundation Medicine, Inc., 150 Second Street, Cambridge, MA 02141, USA. This includes the following data:

- Genomic sequencing data
- Date of birth, gender
- Diagnosis, ICD-O code, stage
- Specimen site
- USZ pathology specimen ID
- Date of biopsy
- Transplant received (yes/no)

Foundation Medicine is certified under the Swiss-U.S. Privacy Shield Framework and therefore committed to data privacy standards equivalent to those provided by Swiss law.

I have read the terms and content of the agreement and hereby order the FoundationOne®CDx Service.

City, Date: _____

Patient, Last name, first name: _____
(in block letters)

Patient, Signature: _____
(legal guardian if a minor)

Information sheet on the further processing of biological material and health-related personal data for research

Version 2.0, December 5, 2016

Dear patient,

In the course of your stay at University Hospital Zurich (USZ), health-related data is collected about you and biological samples (blood and other bodily fluids, tissue samples) may also be collected from your body. This biological material, in combination with the data, is of great value to medical research. For this reason, we would like to ask for your consent to use this material and your data for the purposes of research.

Your consent for the research

With your consent, researchers can use your data in scientific analysis and carry out studies using the biological samples. This consent relates to data from your medical history, such as the results of clinical, imaging and laboratory tests, as well as genetic data (results of tests on genetic make-up), personal details (age, sex), details of treatment you have received and disease progression. The samples relate to existing biological material (blood, urine, or tissue samples) obtained from you for the purposes of your diagnosis or treatment and which is no longer required. Strict regulations govern the use of data and samples and their transfer to researchers in Switzerland or abroad.

You may be asked for consent for research purposes on another occasion during your stay at our hospital. This can happen, for example, if the department providing treatment wishes to obtain additional samples from you for a biobank or as part of an investigation into a specific scientific question. In such cases, your treatment team will provide you with further information.

Protection of your data and samples

Very few people are authorized to view the data in your medical history. These people are responsible for your treatment or have permission to view your data within the context of an approved research project.

Data that is processed for research purposes must be **encrypted** as soon as possible; in other words, all information that refers to your identity – such as your name, date of birth, insurance number, etc – is replaced with a code. As a result, only those with access to the **key** (a document that connects the code with the name) can trace the identity back to you.

The **biological samples** are stored securely in a biobank. A biobank is a systematic collection of samples and linkable data, and is subject to clearly defined conditions. Biological material and genetic data must be passed on to researchers only in **encrypted or anonymized** form. Anonymous means that all identifying information is made indecipherable or deleted, so that it is no longer possible to trace the identity of the person.

Information sheet on the further processing of biological material and health-related personal data for research

If data and samples are passed on to researchers **outside** UniversityHospital Zurich, the key remains at the USZ, where it is held securely by an office not involved in the research project. For research abroad, it must be ensured that at least the same data protection requirements are observed as in Switzerland.

Every research project must be approved by the relevant ethics committee. This committee checks whether the project and its implementation are scientifically and ethically justifiable, and whether the legal conditions, in particular relating to data protection, are respected.

Research results

Findings from research projects involving data and samples usually contribute to improved treatment for future patients. However, if a result is relevant to your personal health, you will be informed if possible (this is not possible with anonymized samples). Such situations occur very rarely.

Provision of your data and samples for research does not entitle you to a share of any potential profits that may result from the findings. **No costs** will be incurred by you or your health insurance provider as a result of the research projects.

Your rights

Your consent is voluntary and in principle applies without limitations. However, you have the right to withdraw your consent at any time without giving a reason (revocation). To do so, please consult the department where you are being treated. In the event of revocation, your data and samples will no longer be handed over to research projects.

Your decision to give consent or not, or to revoke your consent, will have no effect on your medical care.

Additional information

If you have any questions on the further processing of data and material for research, please consult your attending physician or visit our website at www.usz.ch/forschung

Declaration of consent

to the further processing of health-related personal details and biological material for research.

Patient label

Surname and first name of patient:

Date of birth:

I acknowledge that

– I have received the information sheet (version 2.0, December 5, 2016) accompanying this declaration of consent and I am sufficiently informed.

I consent to

– the processing of my health-related data (including genetic data) and biological samples in the form described above for the purposes of research.

☐ **Yes**

☐ **No**

With the provision of your health-related data and material, you are making a valuable contribution to biomedical research.

Thank you very much.

Place

Date . .

Patient's signature

Surname, first name and signature of authorized representative