Department of Pathology and Molecular Pathology
Schmelzbergstrasse 12, 8091 Zurich, Switzerland
Service: fmi.pathologie@usz.ch +41 (43) 253 1818

FoundationOne® Order Form

1. Ordering the FoundationOne®CDx oder FoundationOne®Heme Test

The FoundationOne®CDx test is used for the genomic analysis of tumour tissue. The FoundationOne®Heme test is used for genomic analysis of tumour tissue, blood and bone marrow. Both the FoundationOne®CDx test and the FoundationOne®Heme test (referred to below as FoundationOne® tests) include a detailed report of the mutations found according to the respective gene lists.

The FoundationOne® tests are performed at University Hospital Zurich (USZ) and at Foundation Medicine®, Inc., (FMI) in Cambridge, MA, USA.

Please select the test you would like to order:

☐ FOUNDATIONONE®CDx **Solid tumor test**

FFPE material: Please send the completed order form by fax (+41 44 255 4552) or by email to fmi.pathologie@usz.ch. USZ contacts the referring pathologist to request the biopsy (FFPE material)

☐ FOUNDATIONONE®HEME **Malignant haematological disease and sarcoma test**

Blood or bone marrow aspirate (for malignant haematological diseases): Please follow the instructions in the "Sample Guide for Blood and Bone Marrow Aspirate" and enclose the completed order form in the shipping box. USZ pays the shipping costs.

FFPE material (for sarcomas): Please send the completed order form by fax (+41 44 255 4552) or by email to fmi.pathologie@usz.ch. USZ contacts the referring pathologist to request the biopsy (FFPE material).

☐ **Registration of the patient for consultation at the Tumor Boards of the USZ**

Molecular Tumour Board for solid tumours and sarcomas:	every Thursday	14:00 – 15:00
Tumour Board for malignant haematological diseases:	every Wednesday	16:30 – 17:30

If you wish, we can have a discussion about the patient at the Molecular Tumour Board. You are welcome to attend in person or by telephone. Please send us the relevant clinical documents for the Tumor Board. We will get in touch with you in advance to arrange an exact date.

For questions please contact the Customer Care Service:

Universityhospital Zurich, Department of Pathology and Molecular Pathology
Tel: +41 (43) 253 1818 E-Mail: fmi.pathologie@usz.ch

Questions and information regarding the test results should be addressed directly by the patient to the attending physician.

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2. Ordering Physician

Surname, first name	
Hospital/Prctice/Clinic	
Adress	
Phone / Email (HIN secured)	

I confirm with my signature that I am explicitly requesting potential off-label information specific to the detected genomic alterations as part of the FoundationOne® test.

Date: _____ Signature of the attending physician: _____

3. Referring Pathology, if not from the University Hospital Zurich (FFPE material only)

Surname, first name of the primary finding pathologist	
Hospital/Institute	
Adress	
Phone / Email	

4. Patient Data and Invoice Details

Gender	male ☐ fenmale ☐
Surname, first name	
Date of birth	
Adress	
Health insurance	

Invoice sent to: ☐ Patient ☐ Referring physician ☐ Others: _____
☐ Health insurance _____

Copy of the FoundationOne® report goes to: _____

5. Details of the Specimen

Specimen No.	**Diagnosis**
Location of specimen (organ)	**Disease stage**
Date of specimen collection	**International classification (ICD-O Code)**
Specimen type, fixation (FFPE)	**Has the patient received a transplant?** No ☐ Yes ☐ Please specify _____
Comments/Questions:	

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6. Terms of Contract and Information

Please read the following instructions carefully before ordering our product:

The FoundationOne®CDx and FoundationOne®Heme tests (referred to below as FoundationOne® tests): Foundation Medicine®, Inc., has developed the FoundationOne® test and set its performance characteristics. (Foundation Medicine®). The FoundationOne® tests can be used for clinical purposes and are not intended solely for research purposes. The clinical reference laboratory at Foundation Medicine® has been certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform highly complex clinical investigations. The FoundationOne®CDx test has been approved by the United States Food and Drug Administration (FDA).

Diagnostic significance: the FoundationOne® tests detect changes in cancer-associated genes or gene components (biomarkers). In some cases, where clinically relevant, the report also mentions selected biomarkers that have tested negative.

Qualified presentation of results (equivocal and subclonal): when a change is referred to as "amplification – equivocal", it means that the FoundationOne® tests provide some indication, but no clear evidence, that the copy number of a gene exceeds the threshold for identifying amplification. The limit used in the FoundationOne®CDx test to identify copy number amplification is four (4) for ERBB2 and six (6) for all other genes. The limit used in the FoundationOne®Heme test to identify copy number amplification is five (5) for ERBB2 and six (6) for all other genes. Conversely, a change known as "loss – equivocal" means that the FoundationOne® test provides some evidence, but no clear proof, of homozygous deletion of the gene in question. A change classed as "subclonal" was measured using the FoundationOne® test analytical methods as a change present in < 10% of the tumour DNA examined.

Additional information: additional information (e.g. short nucleotide variants, SNVs), the sequencing depth at the modified site, allele frequency, number of DNA copies) is generated during the preparation of each report and can be provided in a table upon request by the oncologist ordering the test. This data is intended for scientific purposes only in pseudonymous form and may not be used for diagnostic interpretations beyond the FoundationOne®CDx or FoundationOne®Heme report. This additional use can be objected to at any time. USZ bears no liability for improper use.

The report contains analyses of peer-reviewed studies and other publicly available information compiled by Foundation Medicine®; this compilation and the information contained therein may represent molecular change (or lack of change) in the context of one or more drugs with potential clinical benefit (or lack of potential clinical benefit), including drug candidates subject to clinical research. The report contains information on drugs approved for the patient's tumour indication as well as information on drugs approved for other indications.

NOTE: a change in a biomarker does not necessarily indicate pharmacological efficacy (or lack thereof) of a drug or therapeutic regimen; no change in a biomarker does not necessarily indicate a lack of pharmacological efficacy (or presence thereof) of a drug or therapeutic regimen.

Changes and drug substances are not listed according to any rank or weighting: in the report, neither changes to the relevant biomarkers nor active substances associated with a potential clinical benefit (or lack thereof) are sorted or weighted according to possible or predicted efficacy.

No level of evidence is given: drugs with potential clinical benefit (or lack thereof) are not evaluated by either the source or level of published evidence.

Clinical benefit is not guaranteed: the report makes no promises and gives no guarantee that a particular drug will be effective in treating the disease in a patient or that a substance with no potential clinical benefit will actually have no clinical benefit.

Reimbursement is not guaranteed: University Hospital Zurich, Foundation Medicine® and Roche make no promises and give no guarantee that a healthcare provider, health insurance company or third party, whether private or public, will reimburse a patient for the costs of the FoundationOne® test.

Therapeutic decisions are the responsibility of the physician: the drugs mentioned in the report may not be suitable for certain patients. The selection of one, all or none of the medicinal products with a potential clinical benefit (or lack thereof) is entirely at the discretion and responsibility of the attending physician. In addition, the information in this report must be considered in conjunction with all other relevant information relating to the individual patient before the attending physician recommends a particular treatment. Information on treatment recommendations of the FoundationOne®CDx test refers to approval of drugs by Swissmedic. Information on treatment recommendations of the FoundationOne®Heme test refers to the approval of drugs by the FDA in the US. It is the responsibility of the attending physician to select an appropriate therapy option based on locally approved therapies and according to the local label of the drug.

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

Certain sample or variant characteristics can lead to reduced sensitivity. These include: subclonal changes in heterogeneous samples, poor sample quality or samples with homozygous gene losses of <3 exons and deletions and insertions >40 bp, or in repetitive / highly homologous sequences. The FoundationOne®CDx test is performed with DNA derived from tumour tissue and the FoundationOne®Heme test with DNA and RNA derived from tumour tissue, blood or bone marrow. Therefore changes in the germ line may not be detected. The following targets typically have low coverage, resulting in reduced sensitivity: SDHD exon 6 and TP53 exon 1.

Exclusion of liability: any liability of USZ is excluded to the extent permitted by law.

Applicable law and place of jurisdiction: Swiss law shall apply exclusively to this order. The place of jurisdiction is Zurich.

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7. Order and Patient Consent Declaration

I agree that my attending physician may pass on my patient data and my biological tumour tissue to University Hospital Zurich, Institute of Pathology and Molecular Pathology, Schmelzbergstrasse 12, CH-8091 Zurich, Switzerland for the purpose of executing and invoicing the treatment order.

The Institute of Pathology and Molecular Pathology, University Hospital Zurich, will perform genomic sequencing and forward the sequencing data along with the required patient information to the laboratory of Foundation Medicine, Inc., 150 Second Street, Cambridge, MA, 02141, USA. The data concerned are as follows:

- Genomic sequencing data
- Date of birth, gender
- Diagnosis, ICD-O code, stage
- Place of sampling
- UHZ Pathology sample number
- Date of sample collection
- Transplant received (yes/no)

Foundation Medicine, Inc. is certified under the "Swiss Privacy Shield" data protection agreement with the US and has committed itself to the same standards of data security as specified in the Swiss Data Protection Act.

I have been advised by my oncologist that indications of possible hereditary germline mutations can be detected by the FoundationOne® test.

I have taken note of the terms and conditions and information and wish to order the FoundationOne® test.

Place, Date: _____

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

Patient signature: _____
(for minors a legal guardian)

Please send the completed form to the University Hospital Zurich.

Fax: +41 44 255 4552

Email: fmi.pathologie@usz.ch

Thank you for your order.

Information sheet

Further use of health-related personal data and biological material for research purposes

Version 3.0 of 01/10/2019, en

Dear Patient

During your stay at University Hospital Zurich (USZ), health-related data and possibly also biological material from your body (samples of blood and other bodily fluids, tissue samples) will be gathered from you.
This biological material in connection with the data is also very valuable for medical research. We therefore ask for your consent to use this material and your data for research purposes.

Your consent for research purposes

With your consent, researchers can scientifically analyse your data and conduct tests on samples that have been taken from you. This consent concerns data at our hospital that relate to your health or person. This includes entries in your medical history concerning the course of disease and treatments you have received, results of imaging examinations or laboratory testing, details of your genetic predisposition to certain illnesses (genetic data) and details about your person (age, gender).
The samples involve previously removed biological material (blood, urine or tissue) that is no longer required for the purposes of diagnosis or treatment.

It is possible that during the course of your stay at our hospital you will be asked again to provide consent for research purposes. This may be the case if the clinic that is responsible for you wishes to take additional samples from you or scientifically examine a specific issue.

Protection of your data and samples
The use of the data and samples and their forwarding to researchers in Switzerland and abroad are subject to strict regulations. Only a small number of people are authorised to view your medical history. These people are responsible for your treatment or have permission within the framework of a research project to view your data.

Data used for research purposes must be **coded** as swiftly as possible, meaning that all identifying details – such as your name, date of birth, insurance number, etc. – are replaced by a code. Only people with access to the key (a document matching codes and names) can thus associate them with your person.

The **samples (biological material)** are stored securely in a biobank. A biobank is a systematic collection of samples and associable data stored under clearly stipulated conditions. Samples and genetic data may only be passed on to researchers if they are **coded or** anonymised. Anonymised means that all the identifying details have either been rendered unrecognisable or deleted so that it is no longer possible to trace them back to your person.

Forwarding of your data and samples
If data and samples are forwarded in coded form to researchers **outside** University Hospital Zurich, the key will remain at USZ, where it will be stored securely by an office not involved in the research project. For research conducted abroad, it must be ensured that at least the same data protection requirements are upheld that apply in Switzerland.

In general, research projects must also be approved by the local ethics committee. This assesses whether the project and its conduct are scientifically and ethically sound, and whether the legal requirements, in particular data protection, are complied with.

Research results
The findings from research projects involving data and samples usually contribute to improved medical care only for future patients. If, however, certain results should prove relevant for your own health, you will be informed of this as far as possible (this is not feasible in research with anonymised samples). However, such situations occur very rarely.

By volunteering your data and samples for research purposes, you waive the right to any share in possible profits that could arise from the results. Neither you nor your health insurer will incur **any costs** resulting from the research projects.

Your rights
Your consent is voluntary and generally has no expiration. However, you are entitled at any time to withdraw your consent without stating the reasons **(revocation)**. To do so, please contact the clinic treating you. In the event of revocation your data and samples will no longer be made available for researchprojects.

Deciding for or against granting your consent and withdrawing your consent will have no effect on your medical car.

→ **Should you have any other questions about the further use of your data and samples for research purposes, please contact the doctor treating you or visit our website www.en.usz.ch/research**

Declaration of consent

to the further use of health-related personal data and biological material for research purposes

Patient label

Last name and first name of patient:

Date of birth:

I confirm that

– I have received the information sheet that is part of this declaration of consent, and feel sufficiently informed.

I consent to

– the further use of my health-related data (incl. genetic data) and biological material as described above for research purposes.

☐ **Yes**

☐ **No**

By permitting the use of your health-related data and samples, you are making a valuable contribution to biomedical research.

Thank you very much for this.

Town/city

Date . .

Patient signature

Only if a minor or without legal capacity:
Signature of authorised representative