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

FOUNDATIONONE®

Order Form

1. Ordering of the FoundationOne® Service

The FoundationOne 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® 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	

Which information would you like to receive in the report (please check as appropriate):

❑ **Approved therapies for the patient's tumour type**

❑ **Approved therapies for other tumour types** ❑ **Possible clinical trials**

Note: For various reasons, the product information and the clinical studies are not provided in full in the report. The full drug information can be found at *www.swissmedicinfo.ch*

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 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® Service: The FoundationOne® service was developed and its performance characteristics were defined by Foundation Medicine, Inc. (Foundation Medicine). The FoundationOne® 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® service has neither been approved by nor received marketing authorisation from the United States Food and Drug Administration (FDA). The FDA has declared that such an approval or marketing authorisation is not required (based on US regulatory guidelines).

Diagnostic significance: The FoundationOne® 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® 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® 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® 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® 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® 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® Service.

City, Date: _____

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

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