FOUNDATIONONE®CDx

ORDER FORM

Please email to norway.foundationmedicine@roche.com or fax to +47 22 78 90 51

Please fill in carefully in capital letters – unclarities may cause delays

Service (please indicate which service you are ordering)	**Supplemental Service**
☐ FOUNDATIONONE®CDx ☐ FOUNDATIONONE®LIQUID	☐ IHC Testing PD-L1 FFPE tissue

Treating physician at ordering clinic

Office/Practice/Institution Name

Treating physician

Business Address

Telephone Fax

E-mail

Please tick box:

☐ I acknowledge that I may receive information for 1) approved* therapies in the patient's tumor type, 2) approved* therapies in another tumor type, or 3) potential clinical trials

☐ I hereby confirm that the patient has been informed and provided his/her consent

Signature Treating physician

☐ I hereby confirm that the patient has been informed and provided his/her consent to the processing of his/her personal data for purposes of providing the service

I hereby confirm that the patient has provided his/her consent to the processing of his/her pseudonymized data for research and scientific purposes. ☐ YES ☐ NO

Responsible Pathologist

Office/Practice/Institution Name

Responsible Pathologist

Business Address

Telephone Fax

E-mail

Invoicing and Payment

Invoice will be issued at receipt of the Report, in accordance with standard payment terms as agreed between the ordering clinic and Roche Norge AS.

I hereby confirm the legally binding order of FoundationOne® for

_____ (name of ordering clinic)

at a price of 37 097 NOK exluding value added tax, 46 371,70 NOK including value added tax

I also confirm that the responsible pathologist is informed and willing to provide the required specimen for the analysis.

_____

Signature Treating Physician

* Approved by the FDA for the U.S. market

FOUNDATION MEDICINE®

Roche

Roche is the licensed distributor of Foundation Medicine products outside of the United States

Roche Norge AS
Brynsengfaret 6B
NO-0667 Oslo
Postboks 6610 Etterstad
0607 Oslo
Telephone: +47 22 78 90 50
Corporate identity 935 925 525

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Please note when ordering

Please carefully read the following general terms before ordering our product.

General Terms

FoundationOne: FoundationOne was developed and its performance characteristics determined by Foundation Medicine, Inc. (Foundation Medicine). FoundationOne has not been cleared or approved by the United States Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. FoundationOne may be used for clinical purposes and should not be regarded as purely investigational or for research only. Foundation Medicine's clinical reference laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing.

Diagnostic Significance: FoundationOne identifies alterations to select cancer-associated genes or portions of genes (biomarkers). In some cases, the Test Report also highlights selected negative test results regarding biomarkers of clinical significance.

Qualified Alteration Calls (Equivocal and Subclonal): An alteration denoted as "amplification – equivocal" implies that the FoundationOne assay data provide some, but not unambiguous, evidence that the copy number of a gene exceeds the threshold for identifying copy number amplification. The threshold used in FoundationOne for identifying a copy number amplification is five (5) for ERBB2 and six (6) for all other genes. Conversely, an alteration denoted as "loss – equivocal" implies that the FoundationOne assay data provide some, but not unambiguous, evidence for homozygous deletion of the gene in question. An alteration denoted as "subclonal" is one that the FoundationOne analytical methodology has identified as being present in <10% of the assayed tumor DNA.

The Report incorporates analyses of peer-reviewed studies and other publicly available information identified by Foundation Medicine; these analyses and information may include associations between a molecular alteration (or lack of alteration) and one or more drugs with potential clinical benefit (or potential lack of clinical benefit), including drug candidates that are being studied inclinical research.

NOTE: A finding of biomarker alteration does not necessarily indicate pharmacologic effectiveness (or lack thereof) of any drug or treatment regimen; a finding of no biomarker alteration does not necessarily indicate lack of pharmacologic effectiveness (or effectiveness) of any drug or treatment regimen.

Alterations and Drugs Not Presented in Ranked Order: In this Report, neither any biomarker alteration, nor any drug associated with potential clinical benefit (or potential lack of clinical benefit), are ranked in order of potential or predicted efficacy.

Level of Evidence Not Provided: Drugs with potential clinical benefit (or potential lack of clinical benefit) are not evaluated for source or level of published evidence.

No Guarantee of Clinical Benefit: This Report makes no promises or guarantees that a particular drug will be effective in the treatment of disease in any patient. This Report also makes no promises or guarantees that a drug with potential lack of clinical benefit will in fact provide no clinical benefit.

Treatment Decisions are Responsibility of Physician: Drugs referenced in this Report may not be suitable for a particular patient. The selection of any, all or none of the drugs associated with potential clinical benefit (or potential lack of clinical benefit) resides entirely within the discretion of the treating physician. Indeed, the information in this Report must be considered in conjunction with all other relevant information regarding a particular patient, before the patient's treating physician recommends acourse of treatment.

Decisions on patient care and treatment must be based on the independent medical judgment of the treating physician, taking into consideration all applicable information concerning the patient's condition, such as patient and family history, physical examinations, information from other diagnostic tests, and patient preferences, in accordance with the standard of care in a given community. A treating physician's decisions should not be based on a single test, such as this Test, or the information contained in this Report.

Certain sample or variant characteristics may result in reduced sensitivity. These include: sub clonal alterations in heterogeneous samples, low sample quality or with homozygous losses of < 3 exons; and deletions and insertions > 40 bp, or in repetitive/high homology sequences. FoundationOne is performed using DNA derived from tumor, and as such germline events may not bereported. The following targets typically have low coverage resulting in a reduction in sensitivity: SDHD exon 6 and TP53 exon 1.

For additional information please call Roche Customer Care: +47 22 78 90 50

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Postboks 6610 Etterstad
0607 Oslo
Telephone: +47 22 78 90 50
Corporate identity 935 925 525