FOUNDATIONONE® CDx FOUNDATIONONE® LIQUID FOUNDATIONONE® HEME

ORDER FORM

This order applies to: ☐ **FoundationOne CDx** ☐ **FoundationOne Liquid** ☐ **FoundationOne Heme**

Please send to e-mail address: stockholm.foundationmedicine@roche.com

TREATING PHYSICIAN AT ORDERING CLINIC

Be careful to fill in accurate letters if writing by hand - unclear handwriting may cause delays

Office/Practice/Institution Name*

Treating Physician*

Business Address*

Telephone*

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 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 ☐

Signature **TREATING PHYSICIAN**

*Approved by EMA in the European market

RESPONSIBLE PATHOLOGIST (When ordering FoundationOne CDx and FoundationOne Heme)

Office/Practice/Institution Name*

Treating Pathologist*

Business Address*

Telephone*

E-mail*

INVOICING AND PAYMENT - please choose one of the two options and sign below

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

☐ **I hereby confirm the legally binding order of FoundationOne® CDx FoundationOne® Liquid when ordering clinic pays at a price of 20 229 SEK excluding value added tax. unless otherwise agreed in writing with Roche AB.**

☐ **I hereby confirm the legally binding order of FoundationOne® Heme at a price of 25 229 SEK, excluding value added tax, unless otherwise agreed in writing with Roche AB.**

Name of ordering clinic

☐ **I hereby confirm the legally binding order of FoundationOne® CDx/FoundationOne® Liquid/FoundationOne® Heme when the patient will pay for the test, invoice through Christinakliniken.**

Signature **TREATING PHYSICIAN**

*Mandatory field to fill

Dina personuppgifter. Roche AB lagrar och använder de personuppgifter som insamlas från dig för administrering av ditt ärende. Om du väljer att lämna din e-postadress samtycker du till att e-post används för kommunikation med dig i detta ärende. Läs mer här: www.rocheonline.se/sv_se/privacy-policy.html

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FOUNDATIONONE®CDx FOUNDATIONONE®LIQUID FOUNDATIONONE®HEME

Please note when ordering

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

General Terms applies to both FoundationOne CDx, FoundationOne Liquid and FoundationOne Heme

FoundationOne CDx/FoundationOne Liquid/ FoundationOne Heme was developed and its performance characteristics determined by Foundation Medicine, Inc. (Foundation Medicine). FoundationOne CDx, FoundationOne Liquid and FoundationOne Heme has been approved by the United States Food and Drug Administration (FDA). Foundation Medicine's services 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 Liquid and FoundationOne Heme 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 Foundation Medicine assays data provide some, but not unambiguous, evidence that thecopy number of a gene exceeds the threshold for identifying copy number amplification. For instance, the threshold used in FoundationOne CDx 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 CDx assay data provide some, but notunambiguous, evidence for homozygous deletion of the gene in question. An alteration denotedas "subclonal" is one that the FoundationOne CDx 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 i nformation 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 a ssociated 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 a course of treatment. Decisions on patient care and treatment must be based on the independent medical judgement 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 CDx 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: 08-726 11 00

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