

Guide to FoundationOne® CDx and FoundationOne® Liquid CDx Reports

Professional Services Summary Page

The Professional Services summary at the beginning of the report provides information for all of the reported biomarker and genomic findings upfront. It serves as the overview for clinicians to help ensure no findings are missed. This section is not reviewed or approved by the FDA.



The screenshot shows the Professional Services Summary Page of a FoundationOne report. It includes fields for Patient, Physician, Specimen, Tumor Type, Report Date, and Ordered Test #. The main content area is divided into sections for Biomarker Findings, Genomic Findings, and Report Highlights. Callout 1 points to the Report Highlights section. Callout 2 points to the Biomarker Findings section, which is further divided into Therapies with Clinical Relevance (in Patient's Tumor Type) and Therapies with Clinical Relevance (in Other Tumor Type). Callout 3 points to the Variants to Consider for Follow-up Germline Testing in Select Cancer Susceptibility Genes section. Callout 4 points to the Genomic Findings with No Reportable Therapeutic or Clinical Trial Options section.

1 Report Highlights

This feature distills important genomic insights in one easy-to-find place, helping you focus on the key actionable results to inform your patient's treatment plan.

Such key findings may include targeted therapies with **potential resistance**, **germline implications**, **non-targeted therapy implications** and more depending on each patient case.

2 Therapy and Clinical Trial Implications

Therapies for each associated genomic finding are listed in the therapy table. On the left are therapies within your patient's tumor type, and on the right are those with proven clinical benefit in other tumor types. Therapy resistance based on your patient's genomic profile will also be indicated. If there are matched clinical trials, the number of trials and the corresponding report page are listed for each biomarker or genomic finding.

3 Incidental Findings Banners

Identifies potential germline or clonal hematopoiesis alterations that may warrant follow-up testing. The appearance of the germline banner indicates that an alteration has been previously reported in literature or genomic databases as a germline alteration, not that it is a germline alteration in the patient's sample.

4 Genomic Findings with no Reportable Therapeutic or Clinical Trial Options

Identifies number of trials based on your patient's unique genomic profile with page number for quick reference.

Any FDA-approved claims for companion diagnostic (CDx) findings will appear on the FDA-approved claims page, which comes directly after the Professional Services Summary page(s).

 FOUNDATIONONE®CDx

1

Companion Diagnostic (CDx) Findings

- 1

FDA-Approved CDx Claims
List of FDA-approved companion diagnostics associated with your patient's findings.

A companion diagnostic provides essential information for the safe and effective use of a corresponding drug or biological product.

Professional Services Continued

You can find the remainder of the professional services section after the FDA-approved claims page. FoundationOne Liquid CDx reports also include a Variant Allele Frequency (VAF) Percentage Graph and Table with historical results for up to 5 previous tests shown. This feature is not present in FoundationOne CDx reports, where VAF values are displayed in the Biomarker and Genomic Findings section.



BIOMARKER FINDINGS

1

1 Biomarker and Genomic Findings
Following the initial pages of the report, the professional services section goes into more detail about your patient's findings, as well as the context of those findings in the patient's tumor type.



THERAPY

2

2 Therapeutic Options
Clinical evidence associated with therapeutic sensitivity or resistance for identified genomic alterations or biomarkers in the context of the patient's tumor type are discussed in this section.

Professional Services Continued



CLINICAL TRIAL

3 Clinical Trial Information

Detailed information about the clinical trials your patient has been matched to, ranked for the patient based on location and trial phase.

Report Interpretation Assistance

For additional help with report interpretation, please submit a question to our Medical team at <https://foundationmedicine.com/contact> Alternatively, questions can be submitted through “Ask An Expert” feature on your provider portal or by contacting Client Services at (888) 988-3639 or client.services@foundationmedicine.com.

To learn more about our FDA-approved portfolio, go to foundationmedicine.com/portfolio

FoundationOne®CDx and FoundationOne®Liquid CDx are qualitative next-generation sequencing based *in vitro* diagnostic tests for advanced cancer patients with solid tumors and are for prescription use only. FoundationOne®CDx utilizes FFPE tissue and analyzes 324 genes as well as genomic signatures. FoundationOne®Liquid CDx analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes. The tests are companion diagnostics to identify patients who may benefit from treatment with specific therapies in accordance with the therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the tests does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy for testing with FoundationOne®CDx when archival tissue is not available which may pose a risk. Patients being considered for eligibility for therapy based on detection of *NTRK1/2/3* and *ROS1* fusions should only be tested if tissue is unavailable. Patients who are tested with FoundationOne®Liquid CDx and are negative for companion diagnostic mutations should be reflexed to tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if feasible. For the complete label, including companion diagnostic indications and important risk information, please visit www.F1CDxLabel.com and www.F1LCDxLabel.com.



© 2024 Foundation Medicine, Inc. | Foundation Medicine® and FoundationOne® are registered trademarks of Foundation Medicine, Inc.
www.foundationmedicine.com | Tel: 888.988.3639 | Fax: 617.418.2290 | US-PF-2100005 V5.0