Specimen Instructions

FoundationOne®CDx is an extensively validated tissue-based comprehensive genomic profiling service for all solid tumours. FoundationOne®CDx analyses 324 cancer-related genes to provide potentially actionable information to help guide treatment options.1-3

Acceptable Samples

- Formalin-fixed paraffin embedded (FFPE) specimens, including cut slide specimens are acceptable.
- Use standard fixation methods to preserve nucleic acid integrity. 10% neutral-buffered formalin for 6–72 hours is industry standard. DO NOT use other fixatives (Bouins, BS, AZF, Holland’s).
- Do not decalcify.

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Intended Use

FoundationOne®CDx is a next generation sequencing based in vitro diagnostic device for detection of substitutions, insertion and deletion alterations (indels) and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including tumour mutational burden (TMB) and microsatellite instability (MSI) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumour tissue specimens. The test is intended as a companion diagnostic to identify patients who may benefit from treatment with therapies in accordance with the approved therapeutic product labeling. Additionally FoundationOne®CDx is intended to provide tumour mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. For full information on the intended use, assay descriptions, and for detailed performance specifications, refer to the complete FoundationOne®CDx label at rochefoundationmedicine.com

Reference: