FOUNDATIONONE® CDx

Roche

Specimen Instructions

FoundationOne® CDx is an comprehensive genomic profiling service that can help you determine next steps for the care of your patients by accurately detecting all classes of genomic alterations. Below are Specimen Guidelines to help ensure successful genomic profiling.

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, B5, AZF, Holland's).
- Do not decalcify.

☐ **SAMPLE SIZE**

1 When feasible, please send the block + 1 H&E slide.*

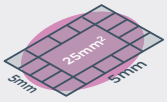
10 unstained slides (positively charged and unbaked at 4-5 microns thick) + 1 H&E slide.*

**For smaller samples, providing the original H&E will preserve material for testing.*

☐ **SURFACE AREA**

2 **MINIMUM: 25 mm²**

If sending slides, provide 10 unstained slides cut at 4-5 microns thick to achieve a tissue volume of 1 mm³.**



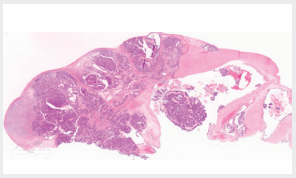
***Specimens with a smaller surface area may meet volume requirements by submitting additional unstained slides (USS) or block.*

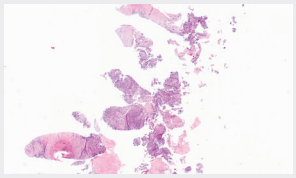
☐ **TUMOUR CONTENT**

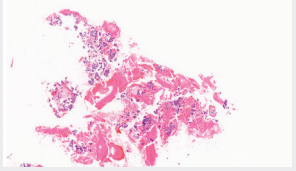
3 **OPTIMUM: 30% TN** **MINIMUM: 20% TN**

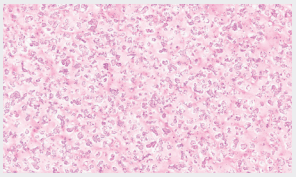
Percent tumour nuclei (%TN) = number of tumour cells divided by total number of all cells with nuclei

Note for liver specimens: higher tumour content may be required because hepatocyte nuclei have twice the DNA content of other somatic nuclei


Resection


Small Biopsy


Fine-Needle Aspiration (Cell Block)


Fluid Exfoliative Cytology (Cell Block)

Intended Use

FoundationOne® CDx (F1CDx) is a next generation sequencing service for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes. F1CDx also assesses select gene rearrangements, and genomic signatures including microsatellite instability (MSI) and tumour mutational burden (TMB) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumour tissue specimens. Additionally, F1CDx 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. The F1CDx assay is a single-site assay performed at Foundation Medicine, Inc.

Roche Products Limited
Hexagon Place, 6 Falcon Way, Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW,
Registered in England 100674

medinfo.uk@roche.com 0800 3281 629

RXUKRFMI00001d(1) Date of Preparation October 2018