

# FoundationOne® CDx Specimen Preparation Instructions

BELOW ARE SPECIMEN GUIDELINES TO HELP SUCCESSFUL GENOMIC PROFILING.

## SELECTING THE BEST SPECIMEN FROM MULTIPLE OPTIONS

Has the patient been treated with targeted therapy?



- Use recurrence or original resection (most recent specimen less than 6 months old preferred).
- Metastasis biopsy or primary tumour acceptable (choose site with highest percent tumour or largest tumour focus).



MUST use post-targeted therapy specimen.

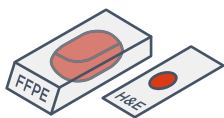
## ACCEPTABLE SAMPLES

- Formalin-fixed, paraffin embedded (FFPE) specimens, including core needle biopsies, fine-needle aspirates and effusion cytologies.
- Tissue should be FFPE. 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 tissue.** When decalcification is required, ethylenediaminetetraacetic acid (EDTA) is recommended. Do not use strong acids (e.g. hydrochloric acid, sulfuric acid, picric acid).

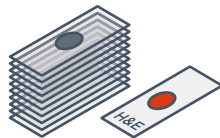
### 1 SAMPLE TYPES

When feasible, please send the block + 1 original (not recut) H&E slide.

10 unstained slides (positively charged and unbaked at 4–5 microns thick) + 1 original (not recut) H&E slide.



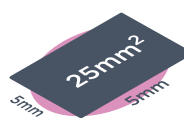
OR



### 2 SAMPLE SIZE SURFACE AREA

**Optimal: 25 mm<sup>2</sup>**  
If sending slides, provide 10 unstained slides cut at 4–5 microns thick.

**Minimal: 5 mm<sup>2</sup>**  
For small (<25 mm<sup>2</sup>) or impure samples, additional unstained slides may be needed to extract sufficient DNA for testing.



OR



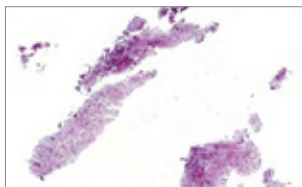
### 3 TUMOUR NUCLEI PERCENTAGE

**Optimal: 30% Minimal: 20%**

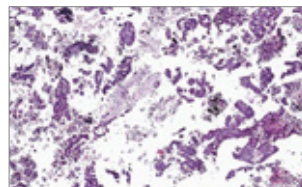
Percent tumour nuclei = number of tumour cells divided by total number of all cells with nuclei.\*



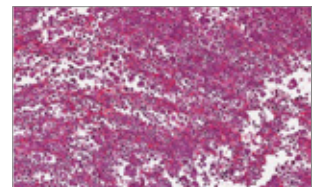
Resection



Small Biopsy



Fine Needle Aspiration (Cell Block)



Fluid Exfoliative Cytology (Cell Block)

\* Note for liver specimens: Minimum tumour content is ≥40%. Since polyploidy is a common characteristic of hepatocytes, twice as many tumour cells would be needed to obtain enough tumour DNA for analysis.

## SHIPPING INSTRUCTIONS

- Place the samples, FoundationOne CDx Requisition Form, pathology report, and any other attachments into the FoundationOne CDx Specimen Kit.
- Place the Specimen Kit (including samples and paperwork) into the provided shipping pack and seal the shipping pack. Ensure any export documentation (Commercial Invoice) is completed and included in the shipping pack.
- Ship sealed shipping pack to: **Foundation Medicine, Inc. 150 Second Street, Cambridge, MA 02141, USA**, by dropping the package at your site's designated FedEx pick up location, or call to request a pickup. The local FedEx contact number is indicated on the top of the shipping pack.

## LOCAL AND REGIONAL CONTACT

Please refer to your country for local contact details.

For more information, contact our APAC Customer Services team: [APAC.foundation@roche.com](mailto:APAC.foundation@roche.com)

AU

Roche Products Pty Limited (Australia)  
Level 8, 30-34 Hickson Road,  
Sydney NSW 2000  
ABN: 70 000 132 865  
Phone: 1800 233 950  
Customer Services team: 1800 800 766  
Email: [sydney.sales@roche.com](mailto:sydney.sales@roche.com)

MY

Roche (Malaysia) Sdn. Bhd.  
Level 21, The Pinnacle, Persiaran Lagoon,  
Bandar Sunway, 47500 Subang Jaya,  
Selangor Darul Ehsan  
Customer Services team: 1800 806 857

HK

Roche Hong Kong Ltd.  
24/F Lee Garden Two,  
2-28 Yun Ping Road, Causeway Bay  
Customer Services team: 800 961 789

NZ

Roche Products New Zealand Ltd.  
98 Carlton Gore Road, Newmarket, Auckland 1023  
Postal Address: PO Box 109113, Newmarket,  
Auckland 1149  
Customer Services team: 0800 880 177

IN

Roche Products (India) Pvt. Ltd.  
1503, 15th Floor, The Capital, Plot No. C-70,  
Behind ICICI Bank Bandra Kurla Complex,  
Bandra (E) Mumbai 400 051  
Customer Services team: 000 800 650 0379

The following promotional material is not valid after 01/04/2020 or any update. For the use of Registered Medical Practitioner or a Hospital or a Laboratory only.

SG

Roche Singapore Pte Ltd.  
1, Kim Seng Promenade #15-07/11,  
Great World City West Tower, Singapore  
237994 Customer Services team: 1800 2255 364

TW

Roche Products Ltd. (Taiwan)  
9th Floor, 134 Minsheng East Road,  
Section 3, Taipei City 105  
Customer Services team: 008 0665 1768

KR

Roche Korea Co. Ltd.  
17th Floor, GT Tower (East), 411 Seocho-daero,  
Seocho-gu, Seoul 06615  
Phone: +82 2 3451 3600  
Customer Services team: 0030 8651 1439

TH

Roche Thailand Ltd.  
89 AIA Capital Center, 26th-27th Floor,  
Ratchadapisek Road, Kwaeng Dindaeng,  
Khet Dindaeng, Bangkok 10400  
Customer Services team: 1800 011 335

