

# Rapid TissueMARK™

LUCENCE

Detecting FDA-Approved Biomarkers For  
Additional 1 in 6 Patients VS Conventional NGS<sup>[1]</sup>

50% of eligible cancer patients miss out on targeted  
therapies from traditional tissue profiling approaches<sup>[2]</sup>

**Rapid TissueMARK™** delivers accurate and affordable  
detection of over 50 DNA/RNA genomic alterations with  
microsatellite instability (MSI) in FFPE tissue

Covering FDA and all CDL-approved<sup>[3]</sup> genetic biomarkers  
for 7 major cancer types

From Asia's first company to obtain US government  
Medicare coverage for NGS testing technology<sup>[4]</sup>

7

Individual  
Tumor Types

18%

More FDA-Approved  
Biomarkers vs  
Conventional NGS<sup>[5]</sup>

5

Working  
Days

## Benefits of Rapid TissueMARK™



**34%** more cost savings from combining mutation NGS  
and MSI for immunotherapy<sup>[6]</sup>



**Save** precious samples, **Save** slide-cutting cost<sup>[7]</sup>



**0.9%** (9 in 1,000) detection limit for superior biomarker  
detection versus conventional and less accurate 5%

## Cancer Types Covered

Common Solid tumor types including Lung, Breast, Ovarian,  
Colon, Pancreas, Bile Duct, Prostate

## Suitable for

- Newly diagnosed patients
- Recurrent and metastatic disease
- Patients who are not responding well to current standard-of-care treatments

[1] Data on file - Comparing 0.9% versus conventional 5% threshold.

[2] Sadik et al. J Clin Oncol Precision Oncology. (2022)

[3] <https://www.moh.gov.sg/home/our-healthcare-system/medishield-life/what-is-medishield-life/what-medishield-life-benefits/cancer-drug-list>

[4] <https://www.businessinsider.com.sg/startups-tech/singapore-lucence-secures-us-medicare-approval-its-cancer-tests>

[5] Data on file - Comparing 0.9% versus conventional 5% threshold.

[6] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9330154/>. Average test is \$1778 + MSI \$600 (add-on). Rapid TissueMARK includes MSI by default.

[7] No splitting of samples required.

# List of FDA-Approved Matched Therapy

| Cancer Type                       | Biomarker            | FDA-approved Matched Therapy                                                                  |
|-----------------------------------|----------------------|-----------------------------------------------------------------------------------------------|
| Lung cancer                       | ALK                  | Alectinib, Brigatinib, Ceritinib, Crizotinib, Lorlatinib                                      |
|                                   | BRAF                 | Binimetinib, Dabrafenib, Encorafenib, Trametinib,                                             |
|                                   | EGFR                 | Afatinib, Amivantamab-vmjw, Dacomitinib, Erlotinib, Gefitinib, Osimertinib                    |
|                                   | ERBB2                | Trastuzumab Deruxtecan                                                                        |
|                                   | ROS1                 | Crizotinib, Entrectinib, Repotrectinib                                                        |
|                                   | RET                  | Pralsetinib, Selpercatinib                                                                    |
|                                   | MET                  | Tepotinib, Capmatinib                                                                         |
|                                   | KRAS                 | Sotorasib                                                                                     |
| Breast cancer                     | AKT1                 | Capivasertib                                                                                  |
|                                   | BRCA1, BRCA2         | Olaparib, Talazoparib                                                                         |
|                                   | PIK3CA               | Alpelisib, Capivasertib                                                                       |
|                                   | ESR1                 | Elacestrant                                                                                   |
|                                   | ERBB2 (HER2)         | Lapatinib, Margetuximab, Neratinib, Pertuzumab, Trastuzumab Emtansine, Trastuzumab, Tucatinib |
|                                   | PTEN                 | Capivasertib                                                                                  |
| Ovarian cancer                    | BRCA1, BRCA2         | Niraparib, Olaparib, Rucaparib                                                                |
| Colorectal cancer                 | BRAF                 | Cetuximab, Encorafenib                                                                        |
|                                   | ERBB2                | Trastuzumab, Tucatinib                                                                        |
|                                   | RAS (Wild-type)      | Cetuximab, Panitumumab                                                                        |
| Pancreatic cancer                 | BRCA1, BRCA2         | Olaparib                                                                                      |
| Cholangiocarcinoma                | FGFR2                | Infigratinib, Pemigatinib                                                                     |
|                                   | IDH1                 | Ivosidenib                                                                                    |
| Prostate cancer                   | BRCA1, BRCA2         | Olaparib, Rucaparib, Talazoparib                                                              |
| Pan-cancer targets <sup>[8]</sup> | NTRK1, NTRK2, NTRK3, | Entrectinib, Larotrectinib                                                                    |
|                                   | BRAF                 | Dabrafenib, Trametinib                                                                        |
|                                   | RET                  | Selpercatinib                                                                                 |
|                                   | MSI                  | Pembrolizumab                                                                                 |

*\*For additional biomarkers : TMB, HRR gene coverage beyond BRCA1/2, and 99.9% coverage of all OncoKB actionable mutations - please upgrade to UNITED™ 600.*

## Test Specifications

|                              |                                                   |
|------------------------------|---------------------------------------------------|
| Methodology                  | Ultra-deep next-generation sequencing             |
| Genomic alterations profiled | SNVs, CNVs, indels, fusions, splice variants, MSI |
| Sample requirement           | FFPE tumor tissue                                 |
| Turnaround time              | 5 working days                                    |

|                                   | Limit of Detection | Sensitivity | Specificity |
|-----------------------------------|--------------------|-------------|-------------|
| Single Nucleotide Variants (SNVs) | 0.9%               | 100%        | 100%        |
| Insertions/Deletions (Indels)     | 1.5%               | 100%        | 100%        |
| Fusions (RNA)                     | 10 copies          | 100%        | 100%        |

• Results tested at the stated mutant allele frequencies using reference standards, and FFPE clinical samples.  
[8] Include drugs with accelerated approval.

Focused genes sub-panels for targeted cancer types

All sub-panels include microsatellite instability (MSI) and RNA fusion testing.

Lung

|                     |                     |                    |                   |                      |                  |                    |
|---------------------|---------------------|--------------------|-------------------|----------------------|------------------|--------------------|
| ALK <sup>#</sup>    | CDKN2A <sup>#</sup> | FGFR2 <sup>#</sup> | MTOR              | NTRK3                | RB1 <sup>#</sup> | STK11              |
| ARAF                | CTNNB1              | FGFR3 <sup>#</sup> | NF1               | PDGFRA <sup>#</sup>  | RET              | TP53 <sup>#1</sup> |
| BRAF <sup>#</sup>   | EGFR <sup>†</sup>   | KEAP1 <sup>†</sup> | NFE2L2            | PIK3CA <sup>#1</sup> | RIT1             | U2AF1              |
| BRCA1 <sup>#1</sup> | ERBB2 <sup>#</sup>  | KRAS <sup>#</sup>  | NRAS <sup>#</sup> | PIK3R1               | ROS1             |                    |
| BRCA2 <sup>#1</sup> | FGFR1 <sup>#</sup>  | MET <sup>#</sup>   | NTRK1             | PTEN <sup>#^</sup>   | SF3B1            |                    |

Breast & Ovarian

|                     |                     |                    |                   |                      |                    |  |
|---------------------|---------------------|--------------------|-------------------|----------------------|--------------------|--|
| AKT1 <sup>†</sup>   | BRCA2 <sup>#1</sup> | ESR1 <sup>#</sup>  | GATA3             | NTRK1                | RB1 <sup>#</sup>   |  |
| APC                 | CDH1                | FBXW7 <sup>#</sup> | GNAS              | NTRK3                | RET                |  |
| ATM <sup>#</sup>    | CDK6 <sup>#1</sup>  | FGFR1 <sup>#</sup> | KRAS <sup>#</sup> | PIK3CA <sup>#1</sup> | SF3B1              |  |
| BRAF <sup>#</sup>   | CTNNB1              | FGFR2 <sup>#</sup> | MYC <sup>#</sup>  | PIK3R1               | TP53 <sup>#1</sup> |  |
| BRCA1 <sup>#1</sup> | ERBB2               | FGFR3 <sup>#</sup> | NF1               | PTEN <sup>#^</sup>   |                    |  |

Colon

|                   |                    |                    |                   |                      |                    |                     |
|-------------------|--------------------|--------------------|-------------------|----------------------|--------------------|---------------------|
| APC               | CTNNB1             | FGRF1 <sup>#</sup> | KRAS <sup>#</sup> | NRAS <sup>#</sup>    | PIK3R1             | SMAD4 <sup>#1</sup> |
| ATM <sup>#</sup>  | EGFR <sup>†</sup>  | FGRF2 <sup>#</sup> | MLH1              | NTRK1                | PTEN <sup>#^</sup> | TP53 <sup>#1</sup>  |
| BRAF <sup>#</sup> | ERBB2 <sup>#</sup> | FGRF3 <sup>#</sup> | MTOR              | NTRK3                | RAF1               |                     |
| CREBBP            | FBXW7 <sup>#</sup> | JAK1               | MYC <sup>#</sup>  | PIK3CA <sup>#1</sup> | RET                |                     |

Pancreas & Bile Duct

|                    |                     |                    |                   |                   |                    |                    |
|--------------------|---------------------|--------------------|-------------------|-------------------|--------------------|--------------------|
| AKT1 <sup>†</sup>  | BRCA2 <sup>#1</sup> | ERBB2 <sup>#</sup> | HRAS              | MYC <sup>#</sup>  | PIK3R1             | TP53 <sup>#1</sup> |
| APC                | CCND1 <sup>#</sup>  | FGFR1 <sup>#</sup> | IDH1              | NRAS <sup>#</sup> | PTEN <sup>#^</sup> | VHL                |
| ATM <sup>#</sup>   | CCND2 <sup>#1</sup> | FGFR2 <sup>#</sup> | IDH2              | NTRK1             | RET                |                    |
| BRAF <sup>#</sup>  | CDKN2A <sup>#</sup> | FGFR3 <sup>#</sup> | KRAS <sup>#</sup> | NTRK3             | STK11              |                    |
| BRCA1 <sup>†</sup> | CTNNB1              | GNAS               | MET               | PIK3CA            | SMAD4              |                    |

Prostate

|                   |                     |                    |                   |                      |                    |                    |
|-------------------|---------------------|--------------------|-------------------|----------------------|--------------------|--------------------|
| AR <sup>#</sup>   | BRCA1 <sup>#1</sup> | FGFR1 <sup>#</sup> | KRAS <sup>#</sup> | NTRK3                | PTEN <sup>#^</sup> | SPOP               |
| ATM <sup>#</sup>  | BRCA2 <sup>#1</sup> | FGFR2 <sup>#</sup> | MYC <sup>#</sup>  | PIK3CA <sup>#1</sup> | RB1 <sup>#</sup>   | TP53 <sup>#1</sup> |
| BRAF <sup>#</sup> | ERBB2 <sup>#</sup>  | FGFR3 <sup>#</sup> | NTRK1             | PIK3R1               | RET                |                    |

RNA Fusions

|                                |                   |       |                                  |            |         |         |
|--------------------------------|-------------------|-------|----------------------------------|------------|---------|---------|
| ALK                            | DNAJB1-PRKACA     | ETV4  | MET (including exon 14 skipping) | NUTM1      | RSPO3   | TMPRSS2 |
| AR (AR-3/4/7/9 splice variant) | EGFR <sup>†</sup> | ETV5  | MYB-NFIB                         | PAX3-FOXO1 | SLC45A3 |         |
| AXL-MBIP                       | ERBB4             | FGFR1 | NRG1                             | PAX8-PPARG | SSX1    |         |
| BRAF                           | ERG               | FGFR2 | NTRK1                            | RET        | SSX2    |         |
| CLIP1-LTK                      | ESR1              | FGFR3 | NTRK2                            | ROS1       | TFE3    |         |
| CTNNB1-PLAG1                   | ETV1              | FLI1  | NTRK3                            | RSPO2      | THADA   |         |

MSI

|       |       |      |      |      |        |
|-------|-------|------|------|------|--------|
| BAT25 | BAT26 | NR21 | NR24 | NR27 | MONO27 |
|-------|-------|------|------|------|--------|

\*Targeted regions selected to maximize detection of known hotspot mutations, in all clinically relevant exons of tested genes. †Includes sequencing of EGFR kinase and extracellular domain mutations. # Includes detection of gene copy number alterations. ^Full coverage >97% coverage of coding exons.

This test is facilitated through Parkway Laboratories | Contact to order: 69330801/ 62485807 | [sgapadmin@parkwaylabs.com.sg](mailto:sgapadmin@parkwaylabs.com.sg)