

FFPE Rescue - Lab Services



Analyze FFPE samples with low tumor cellularity



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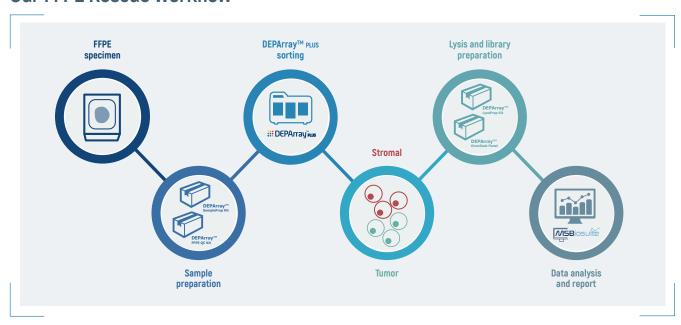


Analyze ANY FFPE sample

NGS analysis of FFPE samples is becoming more widespread in pathology laboratories due to the increasing requirement to identify actionable genes linked to therapeutic targets. DNA tumor content is a critical factor to obtain good data. However not all FFPE samples are suitable for molecular analysis.

DEPArray™ PLUS offers an unprecedent opportunity to overcome the problem of low tumor cellularity in FFPE samples by isolating tumor cells and stromal cells. Recovered cells are used for subsequent downstream analysis, enabling accurate and sensitive molecular characterization.

Our FFPE Rescue workflow



Process samples with less than 5% of tumor cellularity

The failure rate for molecular testing of FFPE samples is more than 8% according to internal market research.

Low tumor content is the primary driver of failed FFPE samples (accounting for 80% of failures as opposed to poor quality of DNA.

Thanks to **DEPArray™ PLUS** you can now RESCUE samples that were discarded in routine pathology labs.





How low can we go with DEPArray FFPE Application?

Four cancer FFPE tissue sections, which were considered not suitable for standard NGS analysis due to low tumor cell content, were successfully analyzed with the **DEPArray FFPE Rescue Workflow**.

Small groups of tumor cells were sorted with DEPArray and subsequently analyzed by NGS using **DEPArray OncoSeek Panel**. Hotspot mutations were identified in the four tumor samples as reported in the table below.

| Tumor | Breast | Breast | Lung | Lung | | |
|----------|-----------|-----------|---------|---------|--|--|
| Sample | 1 | 2 | 3 | 4 | | |
| N cells | 100 | 178 | 113 | 208 | | |
| Reads | 2.535.672 | 1.656.682 | 995.888 | 978.912 | | |
| Coverage | 2.413 | 1.419 | 1.028 | 1.106 | | |



| ooverage | 2.410 | 1.415 | 1.020 | 1.100 | | | | |
|----------|-------|-------|-------|-------|---------|--------------|--------------------|---------------------------------|
| Gene | | | | | Hotspot | Variant-type | Effect | Var |
| TP53 | 92,88 | 0,00 | 0,00 | 0,00 | True | SNV | Stop_gained | chr17:7577142:C:A |
| PIK3CA | 57,18 | 0,00 | 0,00 | 0,00 | True | SNV | Missense_variant | chr3:178936091:G:A |
| TP53 | 0,00 | 85,12 | 0,00 | 0,00 | True | SNV | Missense_variant | chr17:7578551:A:G |
| PTEN | 0,00 | 50,38 | 0,00 | 0,00 | False | Deletion | Frameshift_variant | chr10:89690819:TA:- |
| EGFR | 0,00 | 0,00 | 36,86 | 0,00 | True | Deletion | Frameshift_variant | chr7:55242468:ATTAAGAGAAGCAAC:- |
| TP53 | 0,00 | 0,00 | 0,00 | 29,12 | True | SNV | Missense_variant | chr17:7577548:C:T |

The table presents the variant frequencies detected in small tumor cells populations obtained with DEPArray sorting.

DEPArray FFPE Rescue Application allowed identification of putative actionable mutations in FFPE that were discarded due to low tumor cellularity.

KEY BENEFITS

Powerful

Analyze any FFPE sample regardless of its tumor cellularity (%).

Precise

Succesfully sort small groups of 100-300 cells for NGS analysis.

Easy

Obtain precise information on tumor mutations in a comprehensive report.



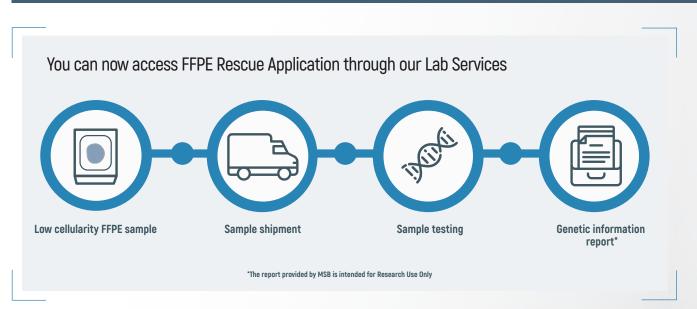
Target sequencing of FFPE sorted populations

DEPArray OncoSeek Panel is conceived for the preparation of high-quality targeted NGS libraries from FFPE cell populations isolated with the DEPArray technology and for the simultaneous detection of single nucleotide variants (SNVs), insertion-deletion (indels) and copy number alterations (CNAs) from 63 oncology relevant genes. Starting from a very low amount of input DNA you can analyze around 100-300 FFPE cells.

| ABL1 5 CDK4 10 ERBB4 8 GNA11 2 KDR 9 MYCN 9 RET 6 AKT1 12 CDK6 10 EXH2 1 GNAQ 2 KIT 24 NOTCH1 3 SMAD4 10 ALK 12 CDKN2A 2 FBXW7 6 GNAS 2 KRAS 11 NPM1 1 SMARCB1 4 APC 9 CSF1R 2 FGFR1 12 HNF1A 4 MAP2K1 5 NRAS 3 SMO 5 AR 10 CTNNB1 1 FGFR2 13 HRAS 2 MET 16 PDGFRA 13 SRC 1 ATM 19 DDR2 1 FGFR3 14 IDH1 1 MLH1 1 PIK3CA 19 STK11 5 BRAF 12 DNMT3A 1 FGFR4 9 IDH2 2 MPL 1 PTEN 14 TP53 21 CCND1 8 EGFR 19 FLT3 4 JAK2 2 MSH6 4 PTPN11 2 TSC1 1 CDH1 3 ERBB2 14 FOXL2 1 JAK3 3 MYC 9 RB1 12 VHL 3 | | | | | | | | | | | | | | |
|--|-------|----|--------|----|-------|----|-------|---|--------|----|--------|----|---------|----|
| ALK 12 CDKN2A 2 FBXW7 6 GNAS 2 KRAS 11 NPM1 1 SMARCB1 4 APC 9 CSF1R 2 FGFR1 12 HNF1A 4 MAP2K1 5 NRAS 3 SMO 5 AR 10 CTNNB1 1 FGFR2 13 HRAS 2 MET 16 PDGFRA 13 SRC 1 ATM 19 DDR2 1 FGFR3 14 IDH1 1 MLH1 1 PIK3CA 19 STK11 5 BRAF 12 DNMT3A 1 FGFR4 9 IDH2 2 MPL 1 PTEN 14 TP53 21 CCND1 8 EGFR 19 FLT3 4 JAK2 2 MSH6 4 PTPN11 2 TSC1 1 | ABL1 | 5 | CDK4 | 10 | ERBB4 | 8 | GNA11 | 2 | KDR | 9 | MYCN | 9 | RET | 6 |
| APC 9 CSF1R 2 FGFR1 12 HNF1A 4 MAP2K1 5 NRAS 3 SMO 5 AR 10 CTNNB1 1 FGFR2 13 HRAS 2 MET 16 PDGFRA 13 SRC 1 ATM 19 DDR2 1 FGFR3 14 IDH1 1 MLH1 1 PIK3CA 19 STK11 5 BRAF 12 DNMT3A 1 FGFR4 9 IDH2 2 MPL 1 PTEN 14 TP53 21 CCND1 8 EGFR 19 FLT3 4 JAK2 2 MSH6 4 PTPN11 2 TSC1 1 | AKT1 | 12 | CDK6 | 10 | EXH2 | 1 | GNAQ | 2 | KIT | 24 | NOTCH1 | 3 | SMAD4 | 10 |
| AR 10 CTNNB1 1 FGFR2 13 HRAS 2 MET 16 PDGFRA 13 SRC 1 ATM 19 DDR2 1 FGFR3 14 IDH1 1 MLH1 1 PIK3CA 19 STK11 5 BRAF 12 DNMT3A 1 FGFR4 9 IDH2 2 MPL 1 PTEN 14 TP53 21 CCND1 8 EGFR 19 FLT3 4 JAK2 2 MSH6 4 PTPN11 2 TSC1 1 | ALK | 12 | CDKN2A | 2 | FBXW7 | 6 | GNAS | 2 | KRAS | 11 | NPM1 | 1 | SMARCB1 | 4 |
| ATM 19 DDR2 1 FGFR3 14 IDH1 1 MLH1 1 PIK3CA 19 STK11 5 BRAF 12 DNMT3A 1 FGFR4 9 IDH2 2 MPL 1 PTEN 14 TP53 21 CCND1 8 EGFR 19 FLT3 4 JAK2 2 MSH6 4 PTPN11 2 TSC1 1 | APC | 9 | CSF1R | 2 | FGFR1 | 12 | HNF1A | 4 | MAP2K1 | 5 | NRAS | 3 | SM0 | 5 |
| BRAF 12 DNMT3A 1 FGFR4 9 IDH2 2 MPL 1 PTEN 14 TP53 21 CCND1 8 EGFR 19 FLT3 4 JAK2 2 MSH6 4 PTPN11 2 TSC1 1 | AR | 10 | CTNNB1 | 1 | FGFR2 | 13 | HRAS | 2 | MET | 16 | PDGFRA | 13 | SRC | 1 |
| CCND1 8 EGFR 19 FLT3 4 JAK2 2 MSH6 4 PTPN11 2 TSC1 1 | ATM | 19 | DDR2 | 1 | FGFR3 | 14 | IDH1 | 1 | MLH1 | 1 | PIK3CA | 19 | STK11 | 5 |
| | BRAF | 12 | DNMT3A | 1 | FGFR4 | 9 | IDH2 | 2 | MPL | 1 | PTEN | 14 | TP53 | 21 |
| CDH1 3 ERBB2 14 FOXL2 1 JAK3 3 MYC 9 RB1 12 VHL 3 | CCND1 | 8 | EGFR | 19 | FLT3 | 4 | JAK2 | 2 | MSH6 | 4 | PTPN11 | 2 | TSC1 | 1 |
| | CDH1 | 3 | ERBB2 | 14 | F0XL2 | 1 | JAK3 | 3 | MYC | 9 | RB1 | 12 | VHL | 3 |

Genes with contiguous, overlapping coverage
 Genes with amplicons for CNA calling and SNV calling

DEPArray™ PLUS FFPE Rescue - Lab Services



EU Shipping address

Send the package to the following address: Menarini Silicon Biosystems S.p.A. Via Giuseppe di Vittorio, 21 b/3 40013 Castel Maggiore (BO) ITALY

USA Shipping address

Send the package to the following address: Menarini Silicon Biosystems Inc. 3401 Masons Mill Rd., Suite 100 - Huntingdon Valley, PA 19006

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Genes with comprehensive coding exon
Genes with only amplicons for CNA calling