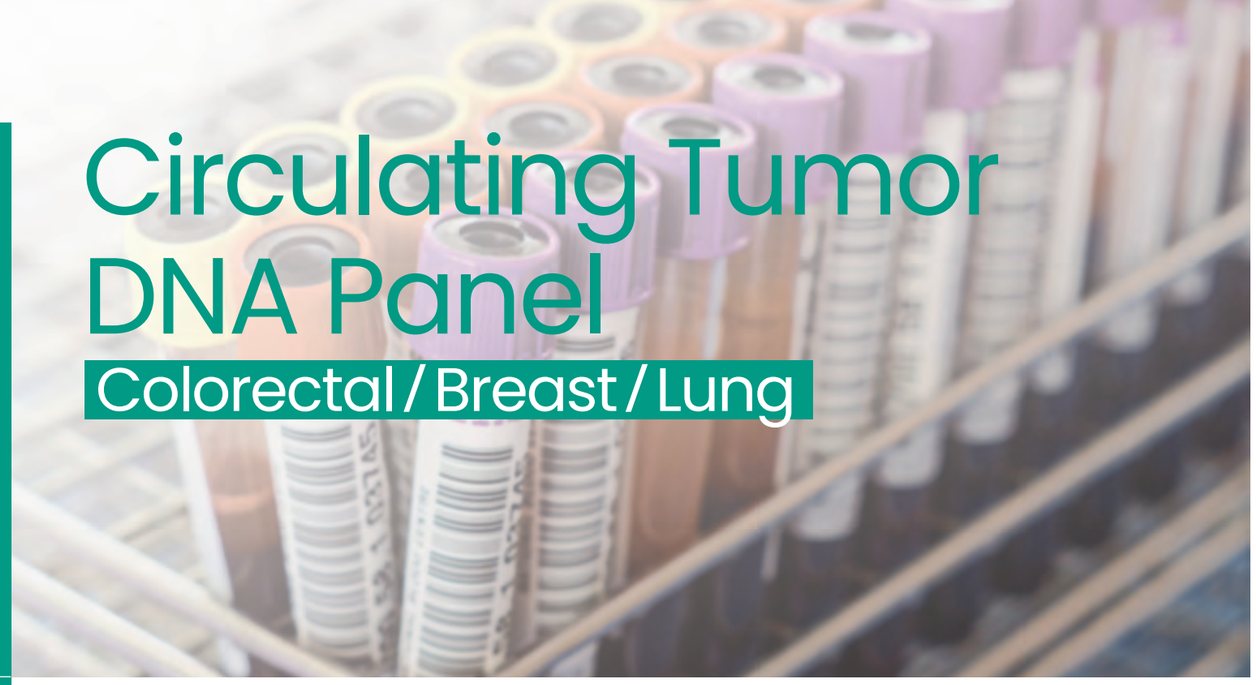


# Circulating Tumor DNA Panel

## Colorectal / Breast / Lung

## OVERVIEW

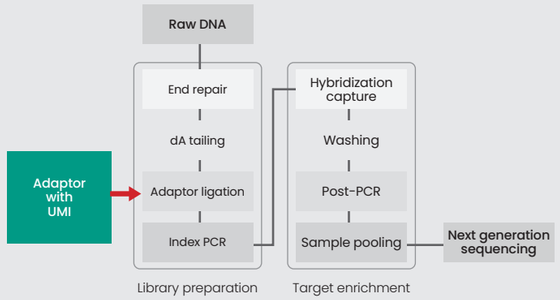
The detection sensitivity for low-frequency variants from a limited amount of sample is of great importance to ctDNA analysis kits. Celemics has developed ctDNA kits for colon, breast, and lung cancer assay through collaborative research with Seoul National University Hospital (SNUH) since 2017. We have integrated our market leading proprietary technologies including probe design algorithms, noise removal techniques, and reagents optimization. The panel is thoroughly validated and ready to use for clinical diagnosis.

## KEY FEATURES

| | |
|---|---|
| **1. Detects ctDNA for Colorectal cancer, Breast cancer, and Lung cancer** | Assess 16 key genes for Colorectal cancer, 27 for Breast cancer, 28 for Lung cancer |
| **2. Highly optimized panel for clinical testing with exceptional accuracy** | Complete validated panel performance conducted with patient samples through collaborative research with Seoul National University Hospital |
| **3. Provides Unique Molecular Identifiers (UMI) and Bioinformatics Software** | Receive high-quality data supported by Celemics proprietary UMI algorithms and analysis software, enabling efficient duplication removal and minimizing sequencing noise |

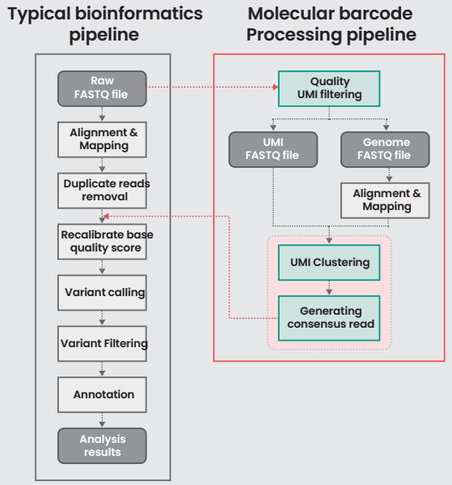


## MODULAR UNIQUE MOLECULAR IDENTIFIER




1. Able to assess ctDNA with ultra-low variant allele frequency (VAF)
2. Retrieves more unique reads than that from conventional duplication removal algorithm, reducing sequencing costs
3. Noise removal and accurate calls possible due to proprietary consensus sequence generation algorithm
4. Modular algorithm to be applied to the existing pipeline.

## MODULAR BIOINFORMATICS PIPELINE




1. Minimizes the noise for accurate analysis of variants from ctDNA with ultra-low VAF
2. Generates consensus reads to support noise suppression
3. Continuous improvement of the noise removal technology by data accumulation

## PACKAGE COMPOSITION

| Package name | Compositions | | |
|---|---|---|---|
| Target Enrichment | Target capture Probe | - | |
| Standard | Target Enrichment reagents | Library prep Kit | - |
| All-In-One | | | Beads / Polymerase |

| Package option | Options | |
|---|---|---|
| Pooling method | Single Reaction | Pre-capture Pooling |
| Library Preparation kits | Standard Kit | EP-kit |
| Hybridization Enhancer | Included | Not included |

# Circulating-tumor DNA Colorectal Cancer Panel

## SPECIFICATION

| | |
|---|---|
| **Gene count*** | 16 genes |
| **Covered region** | Whole CDS |
| **Target size** | 18 kb |
| **Mutation type** | SNV, Indel, CNV |
| **Sample type (amount)** | Plasma (> 20 ng of cfDNA) |
| **Platform** | All sequencers from Illumina and MGI |
| **Bioinformatics pipeline** | 1. Primary and Secondary analysis result (FASTQ to VCF)<br>2. Tertiary analysis result (VCF to Clinical report)<br>3. Linux-based consensus read generation software provided |

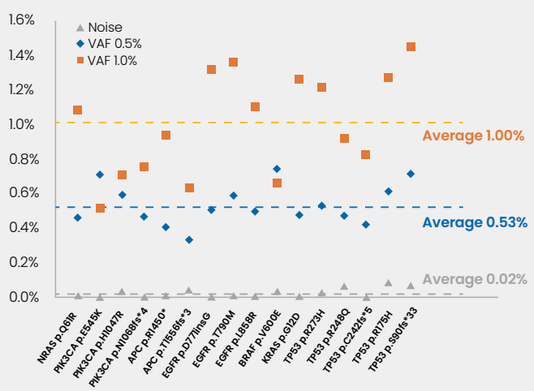
* Gene Add-on Service: Genes can be added or removed by customer demand

## GENE LIST

| ctDNA Panel Colorectal Cancer | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | APC | BRAF | EGFR | ERBB2 | ERBB3 | FGFR1 | HRAS | IRS1 | KRAS | KRAS | MET | NRAS | PDGFRB |
| | PIK3CA | PTEN | TP53 | | | | | | | | | | |

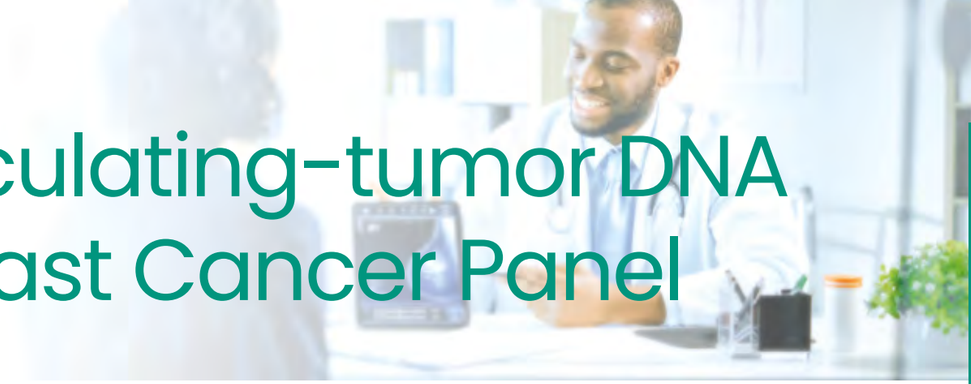
## PANEL PERFORMANCE

Detection of 16 variants with 100% sensitivity and 97.9% specificity at 0.5% VAF and 1% VAF




| | |
|---|---|
| Sensitivity, AF 0.5% | 100% |
| Sensitivity, AF 1.0% | 100% |
| Specificity | 97.9% |





# Circulating-tumor DNA Breast Cancer Panel

## SPECIFICATION

| | |
|---|---|
| **Gene count*** | 27 genes |
| **Covered region** | Whole CDS |
| **Target size** | 99 kb |
| **Mutation type** | SNV, Indel, CNV |
| **Sample type (amount)** | Plasma (> 20 ng of cfDNA) |
| **Platform** | All sequencers from Illumina and MGI |
| **Bioinformatics pipeline** | 1. Primary and Secondary analysis result (FASTQ to VCF)<br>2. Tertiary analysis result (VCF to Clinical report)<br>3. Linux-based consensus read generation software provided |

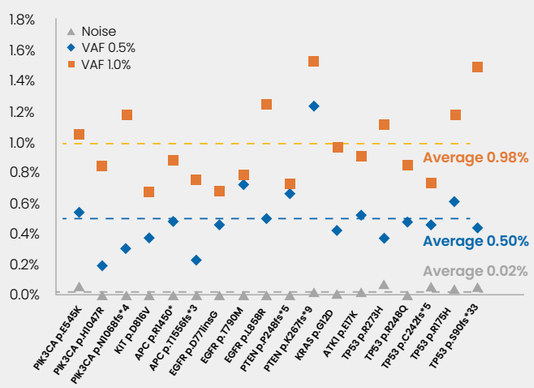
* Gene Add-on Service: Genes can be added or removed by customer demand

## GENE LIST

| ctDNA Panel Breast Cancer | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | AKT1 | APC | AR | BRCA1 | BRCA2 | CCND1 | CDH1 | EGFR | ERBB2 | ESR1 | FGFR1 | FGFR2 | GATA3 |
| | IGF1R | KIT | KRAS | MAP2K4 | MAP3K1 | MDM2 | MYC | NF1 | PIK3CA | PIK3R1 | PTEN | RB1 | TOP2A |
| | TP53 | | | | | | | | | | | | |

## PANEL PERFORMANCE

Detection of 27 variants with 96.3% specificity and 94.4% sensitivity at 0.5% VAF and 100% at 1% VAF




| | |
|---|---|
| Sensitivity, AF 0.5% | 94.4% |
| Sensitivity, AF 1.0% | 100% |
| Specificity | 96.3% |

# Circulating-tumor DNA Lung Cancer Panel

## SPECIFICATION

| | |
|---|---|
| **Gene count*** | 28 genes |
| **Covered region** | Whole CDS + 4 intronic regions |
| **Target size** | 116 kb |
| **Mutation type** | SNV, Indel, CNV |
| **Sample type (amount)** | Plasma (> 20 ng of cfDNA) |
| **Platform** | All sequencers from Illumina and MGI |
| **Bioinformatics pipeline** | 1. Primary and Secondary analysis result (FASTQ to VCF)<br>2. Tertiary analysis result (VCF to Clinical report)<br>3. Linux-based consensus read generation software provided |

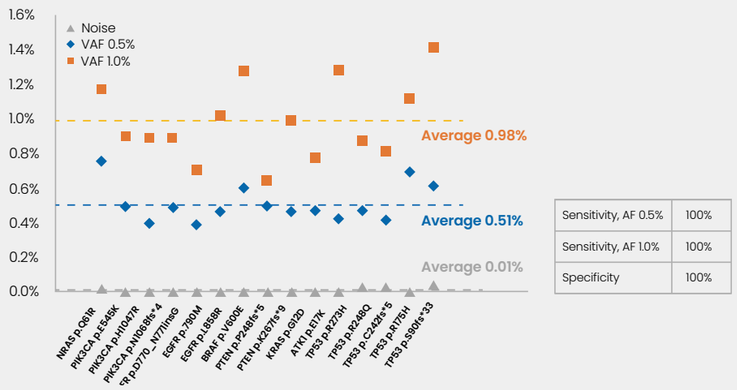
* Gene Add-on Service: Genes can be added or removed by customer demand

## GENE LIST

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ctDNA Panel Lung Cancer | AKT1 | ALK | ARAF | ARID1A | BRAF | CBL | CDKN2A | EGFR | ERBB2 | HRAS | KEAP1 | KRAS | MAP2K1 |
| | MET | MTOR | NF1 | NRAS | NTRK1 | NTRK2 | PIK3CA | PTEN | RB1 | RIT1 | ROS1 | SETD2 | STK11 |
| | TP53 | U2AF1 | | | | | | | | | | | |

## PANEL PERFORMANCE

Detection of 28 variants with 100% sensitivity and 100% specificity at 0.5% VAF and 1% VAF detection




| | |
|---|---|
| Sensitivity, AF 0.5% | 100% |
| Sensitivity, AF 1.0% | 100% |
| Specificity | 100% |

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