# Focus Cancer Panel

## Test Description:

The Focus Cancer Panel (FCP) is a highly multiplexed targeted Next Generation Sequencing (NGS) test, designed to detect somatic mutations in 50 clinically relevant oncogenes and tumor suppressor genes. Variant types covered by the test include single nucleotide polymorphisms (SNPs), multi-nucleotide polymorphisms (MNPs) and insertions and deletions (INDELs).

The FCP test utilizes the capabilities of NGS to provide physicians with a rapid turnaround targeted DNA sequencing service. The concise and easy to understand final report includes identification of genetic alterations, fully annotated and reviewed by our oncologist and pathologist review team. Our analysis pipeline searches multiple curated databases including FDA, NCCN, ASCO and MCG providing physicians with drug response information. This includes listing drugs of known relevance (those with known sensitivity and those associated with resistance associated with the identified variants) and identification of potentially relevant targeted clinical trials.

## Genes Included:

The TNCP investigates genomic hotspot regions including over 2,800 COSMIC mutations from the 50 oncogene and tumor suppressor genes shown below.

| | | | | |
|---|---|---|---|---|
| *ABL1* | *AKT1* | *ALK* | *APC* | *ATM* |
| *BRAF* | *CDH1* | *CDKN2A* | *CTNNB1* | *CSF1R* |
| *EGFR* | *ERBB2* | *ERBB4* | *EZH2* | *FBXW7* |
| *FGFR1* | *FGFR2* | *FGFR3* | *FLT3* | *GNA11* |
| *GNAQ* | *GNAS* | *HNF1A* | *HRAS* | *IDH1* |
| *IDH2* | *JAK2* | *JAK3* | *KDR* | *KIT* |
| *KRAS* | *MET* | *MLH1* | *MPL* | *NOTCH1* |
| *NPM1* | *NRAS* | *PDGFRA* | *PIK3CA* | *PTEN* |
| *PTPN11* | *RB1* | *RET* | *SMAD4* | *SMARCB1* |
| *SMO* | *SRC* | *STK11* | *TP53* | *VHL* |

*Genes shaded blue indicate dual platform (Ion Torrent PGM and Illumina MiSeqDx) testing of targeted regions for that gene. Variants identified in genes covered only by a single platform (e.g. IDH2, EZH2) are assessed during Oncologist/Pathologist variant review prior to reporting.*

## Test Performance Characteristics:

**Assay Sensitivity: Biomarkers for FDA-Approved Labeled Indication**

| Gene | Variant | Limit of Detection |
|---|---|---|
| *BRAF* | V600X | 3.0 |
| *EGFR* | Exon 19 deletion | 2.9 |
| *EGFR* | Exon 21 sub (L858R) | 4.0 |
| *EGFR* | L858R | 4.0 |
| *EGFR* | G719X | 1.9 |
| *ERBB2* | Exon 20 insertion | 5.1 |
| *KRAS* | Codon 12 | 3.4 |
| *KRAS* | Codon 13 | 3.6 |
| *RET* | M918T | 1.9 |

**Test Metrics: Based on routine sample batch sizes**

| PGM | |
|---|---|
| Coverage | >1300X |
| Uniformity | 93% |
| On Target Reads | 98% |
| **Illumina** | |
| Coverage | >2000X |

## Specimen Specifications:

The FCP test has a low tissue input requirement. We request two 1.5ml nuclease free tubes each with 2 x 10 um FFPE scrolls for sequencing. In addition we ask for 1 x H&E stained slide. Embedded tissue within each scroll should have dimensions of at least 7mm x 7mm x 10um. If your tissue does not meet this requirement, please contact us to discuss options to ensure optimum results.

Both slide and tube should be labeled with the patient's name and MRN, accompanied with a completed test requisition form available from (website address). All information must be completed before sample can be processed.

## Contact Information:

For further information, please contact:
CCHMC Pathology, Main Office @ 513-636-4261

## Ship to:

ATTN: Pathology, R2040
Cincinnati Children's Hospital Medical Center
3333 Burnet Ave.
Cincinnati, OH 45229

Scrolls may be sent at room temperature or with an ice pack.
Please ship overnight Monday – Thursday.
No Friday shipments, please.