THE ONCOMINE™ PRECISION ASSAY

PATHOLOGY IS IN OUR DNA

AMPATH LABORATORIES

Precision oncology continues to provide a significant survival benefit to cancer patients by matching biomarker therapy with targetable tumour-specific molecular aberrations. To this end, we offer an improved and more comprehensive solid tumour panel, the Oncomine™ Precision Assay.

What is the Oncomine™ Precision Assay?

The Oncomine™ Precision Assay is a Next Generation Sequencing (NGS) solution that includes all relevant and emerging targets in precision oncology. The following genes are included in the assay:

DNA Hotspots: *AKT1, AKT2, AKT3, ALK, AR, ARAF, BRAF, CDK4, CDKN2A, CHEK2, CTNNB1, EGFR, ERBB2, ERBB3, ERBB4, ESR1, FGFR1, FGFR2, FGFR3, FGFR4, FLT3, GNA11, GNAQ, GNAS, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, NRAS, NTRK1, NTRK2, NTRK3, PDGFRA, PIK3CA, PTEN, RAF1, RET, ROS1, SMO, TP53*

CNVs: *ALK, AR, CD274, CDKN2A, EGFR, ERBB2, ERBB3, FGFR1, FGFR2, FGFR3, KRAS, MET, PIK3CA, PTEN*

Fusions: *ALK, AR, BRAF, EGFR, ESR1, FGFR1, FGFR2, FGFR3, MET, NRG1, NTRK1, NTRK2, NTRK3, NUTM1, RET, ROS1, RSPO2, RSPO3*

How does the Oncomine™ Precision assay differ from the EGFRASSEQ solid tumour panel?

The Oncomine™ Precision Assay offers a significant improvement over our current solid tumour panel:

- **Expanded profile**
  In comparison to the EGFRASSEQ which focuses on mutations in 10 genes, the Oncomine™ Precision Assay enables detection of 2769 unique variants, including mutations, Copy Number Variants (CNVs), and fusion variants, across 50 key genes.
- **Reduced sample requirements and increased sensitivity**
  The Oncomine™ Precision Assay requires only 10 ng of DNA (±3000 cells) or RNA, successfully producing sequencing results in more than 95% of samples.
- **Improved turnaround time with greater clinical impact**
  With the Ion Torrent Genexus™ System, genetic results can be obtained sooner, resulting in earlier initiation of the most appropriate treatment, with enhanced impact and reduced patient anxiety. Turnaround time will fall within international guidelines for NGS-based diagnostics and can be expected in 7-10 working days.
- **Cost saving**
  It is more cost effective to run a single NGS panel than multiple single gene PCR assays.

How does the Precision assay differ from the Focus assay offered by other laboratories?

The Oncomine™ Precision assay should be regarded as an evolution of the Focus assay. There is an updated gene list that emphasises potential future targeted therapies and detects increased and novel fusion isoforms. In addition, the Oncomine™ Precision assay includes 218 potential resistance mutations and is liquid biopsy compatible.

Fast Facts

HOW TO REQUEST:

- Contact the relevant histopathology laboratory where the case was reported
- Request **OPANGS**
- **Special mnemonics are used for Discovery Health Patients and a pre-authorisation code is required:**
  - **OPALUNG** (Lung tumours)
  - **OPACOL** (Colorectal tumours)

TEST RESULTS:

- The electronic report can be expected in 7-10 working days
- A clear and concise report is generated using the Oncomine™ reporter software
- A detailed report including relevant clinical trials is available upon request

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Precision oncology targets with matched agents approved for solid tumours

Tumour type	Target / Biomarker	FDA-approved therapy
Breast cancer	*ERBB2* (HER2) amplification	Herceptin® (trastuzumab), Kadcyla® (ado-trastuzumab-emtansine), or Perjeta® (pertuzumab)
	PIK3CA	Piqray® (alpelisib)
Colorectal cancer	*BRAF* V600E	Braftovi® (encorafinib) in combination with Erbitux® (cetuximab)
	KRAS wild-type (absence of variants in codons 12 and 13)	Erbitux® (cetuximab)
	Both *KRAS* and *NRAS* wild-type	Vectibix® (panitumumab)
Cholangiocarcinoma	*FGFR2* fusions and select rearrangements	Pemazyre™ (pemigatinib) or Truseltiq™ (infigratinib)
GIST	*KIT*	Gleevec™ (imatinib)
Melanoma	*BRAF* V600E	Tafinlar® (dabrafenib) or Zelboraf® (vemurafenib)
	BRAF V600E or V600K	Mekinist® (trametinib) or Cotellic® (cobimetinib), in combination with Zelboraf® (vemurafenib)
Non-Small Cell Lung Carcinoma (NSCLC)	*ALK* rearrangement	Alecensa®(alectinib), Alunbrig® (brigatinib), Xalkori® (crizotinib), or Zykadia® (ceritinib)
	BRAF V600E	Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)
	EGFR Exon 19	Gilotrif® (afatinib), Iressa® (gefitinib), Tagrisso® (osimertinib) or Tarceva® (erlotinib)
	EGFR Exon 20 (T790M)	Tagrisso® (osimertinib)
	EGFR Exon 21 (L858R)	Gilotrif® (afatinib), Iressa® (gefitinib), Tagrisso® (osimertinib) or Tarceva® (erlotinib)
	KRAS G12C	Lumakras™ (sotorasib)
	MET	Tabrecta® (capmatinib)
	RET alteration	Gavreto® (pralsetinib), Retevmo® (selpercatinib)
	ROS1	Xalkori® (crizotinib), Rozlytrek® (entrectinib)
Solid tumours	*NTRK1/2/3* fusions	Vitrakvi® (larotrectinib), Rozlytrek® (entrectinib)
Thyroid carcinoma	*RET* alteration	Gavreto® (pralsetinib)
	BRAF V600E	Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)
Urothelial cancer	*FGFR2/3* altered tumours	Balversa® (erdafitinib)

Cancer treatment has historically followed a one-size-fits-all model. The precision oncology approach takes advantage of recent advances in genome sequencing and offers an unprecedented opportunity to make personalised precision patient care a reality.

For more information, contact us at ngs@ampath.co.za

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