

Pillar[®] oncoReveal[™] Dx Lung and Colon Cancer Assay

One assay for six lung and colon cancer therapies

The first next-generation sequencing (NGS)-based companion diagnostic (CDx) kit that detects somatic mutations in DNA derived from formalin-fixed paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) and colorectal cancer (CRC) tumor tissue. The Pillar oncoReveal Dx Lung and Colon Cancer Assay is intended to be used to select patients with NSCLC or CRC that may benefit from treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling.

Table 1. Intended uses

Indication	Gene	Variant	Targeted Therapy
Colorectal Cancer (CRC)	KRAS	KRAS wild-type (absence of mutations in codons 12 and 13)	Erbix (cetuximab), or Vectibix (panitumumab)
Non-Small Cell Lung Cancer (NSCLC)	EGFR	Exon 19 Deletions Exon 21 L858R	Tarceva (erlotinib), Gilotrif (afatinib), Iressa (gefitinib), or Vizimpro (dacomitinib)

Assay Highlights

▶ One Test, Multiple Therapies

- Establishes eligibility for two CRC therapies and four NSCLC therapies
- Detects clinically relevant mutations in KRAS for CRC and EGFR for NSCLC

▶ Robust Chemistry

- Requires just 10ng DNA
- Sensitive down to just 9.8% tumor content
- Robust to up to 50% contaminating necrotic tissue

▶ Rapid Workflow

- Single-tube workflow with only 2 purification steps
- From sample to sequencer in <8 hours
- Sample to actionable report in <4 days

▶ Powerful bioinformatics

- Detects clinically relevant variants down to 1.6% VAF
- Run time <8 hours
- Calls clinically actionable SNVs and indels

Make treatment decisions faster with multiplex testing

Multiple treatment decisions from one workflow

Testing multiple sample types at the same time allows for treatment decisions in four days for both NSCLC and CRC patients simultaneously.

In-house testing

Up to 48 libraries (2 controls and 46 patient samples) can be sequenced on a single MiSeq[™]Dx cartridge (Illumina Cat. No. 20037124), enabling clinical labs to bring testing in-house instead of sending to third-party labs.

Reduce repeat testing

With low sample-input requirements and extremely robust and sensitive variant detection, the oncoReveal Dx Lung and Colon Cancer Assay reduces the need for repeat testing.

Single-day library preparation

The oncoReveal Dx Lung and Colon Cancer Assay uses Pillar Bioscience's proprietary SLIMamp® chemistry to enable amplification of overlapping amplicons in a single tube. This approach decreases contamination risks and minimizes the amount of required input DNA to just 10ng (see Figure 1). The resulting simplified workflow consists of just two PCR steps and two cleanup steps, so you can go from sample to sequencer in under 8 hours (see Figure 2).

Figure 1. SLIMamp chemistry overview

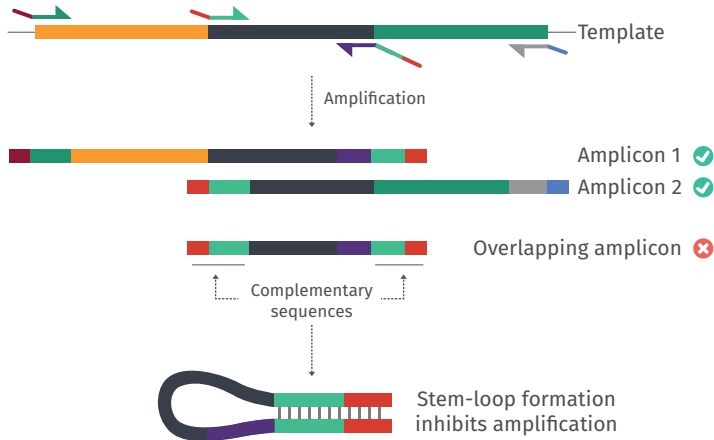


Figure 2. SLIMamp workflow overview



Single day data analysis

The Pillar PiVAT® bioinformatics platform that accompanies the oncoReveal Dx Lung and Colon Cancer Assay is maximized for efficiency and sensitivity, delivering answers in less than 8 hours for variant allele frequencies down to 1.6% with minimal computing resources. The test is accompanied by a workstation (additional purchase required) for intuitive, cyber-secure reporting. The platform's built-in sample sheet tool also makes batching easy.

Reproducible and concordant with previously approved assays

Table 3. Concordance with relevant IVD-cleared assays

Gene	PPA ^a	NPA ^b
EGFR	(91/91) 100%	(163/166) 98.2%
KRAS	(79/81) 97.5%	(103/104) 99.0%

^aNumber of samples with mutation according to Pillar oncoReveal Dx Lung and Colon Cancer Assay divided by the number of samples with mutation according to comparator

^bNumber of samples identified as wild-type by Pillar oncoReveal Dx Lung and Colon Cancer Assay divided by the number of samples identified as wild-type by comparator

Table 4. Reproducibility* data

Gene	True Positives
KRAS variant	(144/144) 100%
EGFR variant	(144/144) 100%
BRAF variant	(72/72) 100%

*Evaluated at 3 sites with 2 operators at each site performing 3 runs on non-consecutive days using 2 reagent lots at each site. Each panel member was tested in 4 replicates in each run for total of 360 possible results.

Ordering information

Product	Part Number
oncoReveal Dx Lung and Colon Cancer Assay, 48 reaction kit	HDA-LC-2002-48
Cyber secure oncoReveal Dx Lung and Colon Cancer Assay PiVAT workstation	SFW-2005
Pillar MiSeqDx LRM Module	SW-0001

Order or learn more at

pillar-biosciences.com

For *In Vitro* Diagnostic Use

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