AmoyDx® Pan Lung Cancer PCR Panel (PLC Panel)

Unleashing the Potential of qPCR: Detect 167 Variants in 11 Genes with a Single Run

Actionable

Detects 167 variants (85 DNA mutations and 82 RNA fusions) in 11 biomarkers recommended by clinical practice guidelines for Non-Small Cell Lung Cancer (NSCLC)

Timely

Fast turnaround time (TAT) from sample receipt to results within 1 day

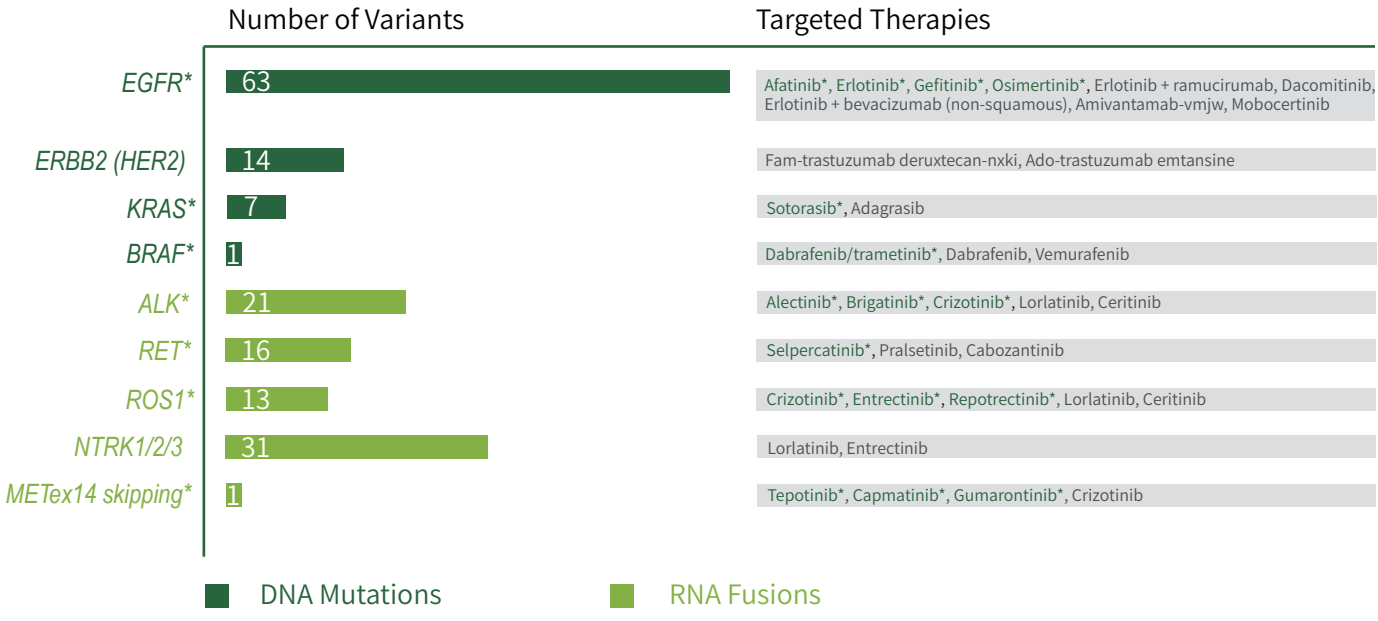
Clinically proven

CE-IVD accredited & PMDA approved companion diagnostic (CDx)

Cost-effective

Aids in the identification of clinically relevant biomarkers for patients with NSCLC who may be eligible for the approved targeted therapies, at minimal cost

PMDA Approved 16 Targeted Therapies with 7 CDx



*Approved by PMDA for targeted therapies (as of September 2024)
PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

Clinical Performance

The clinical performance of PLC Panel was validated in a concordance study by LC-SCRUM-Japan.[1] Results were highly concordant with the reference NGS assay for alterations (fusion, indels, SNVs) across 11 actionable biomarkers.

LC-SCRUM concordance analysis between PLC and reference NGS assay

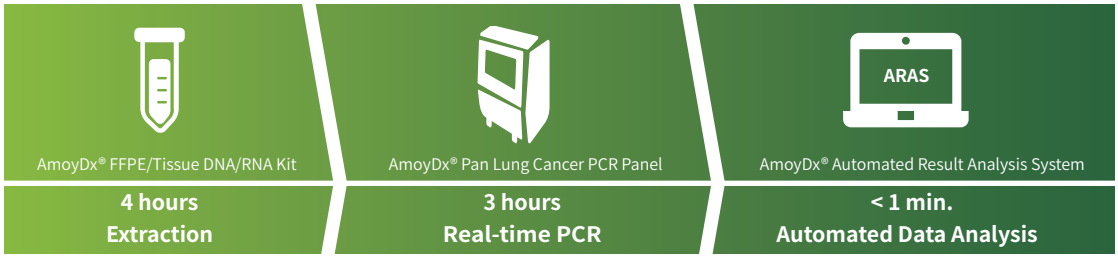
N=2,186		Reference NGS Assay		
		Positive	Negative	Total
PLC Panel	Positive	1,051	33	1,084
	Negative	13	1,089	1,102
	Total	1,064	1,122	2,186
PPA 98.8%, NPA 97.1%, OPA 97.9%				

PPA: positive percent agreement NPA: negative percent agreement OPA: overall percent agreement

Benefits of PLC compared with NGS assays[2]

- Higher success rate
- Higher detection rate
- Shorter turnaround time
- Lower costs

Workflow



Ordering Information

Catalog Number	8.01.0246 (CE-IVD) (QuantStudio™ 5) 8.01.0247 (CE-IVD) (LightCycler® 480 II, cobas z 480) 8.01.0211 (RUO) (QuantStudio™ 5) 8.01.0234 (RUO) (LightCycler® 480 II, cobas z 480, Bio-Rad CFX96) 8.01.0279 (RUO) (SLAN-96S)
Kit Format	8 tests/kit
Limit of Detection	DNA Mutation: 1-5% in 10ng DNA input RNA Fusion: 150 copies/reaction
Sample Requirement	FFPE or Fresh Frozen tissue minimum 60 ng DNA; minimum 120 ng RNA

1. Matsumoto, S., *et. al.* Prospective concordance study of a multi-gene PCR assay and NGS for the detection of targetable gene alterations in lung cancer [abstract] in *Journal of Thoracic Oncology*. 2021 March; 16:3(S690): WCLC; 2020. Abstract P89.06.
2. Kunimasa, K., *et. al.* Clinical application of the AMOY 9-in-1 panel to lung cancer patients. *Lung Cancer.* 2023 May; 179:107190. doi:10.1016/j.lungcan.2023.107190. Epub 2023 Apr 8. PMID: 37058787.

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CE IVD