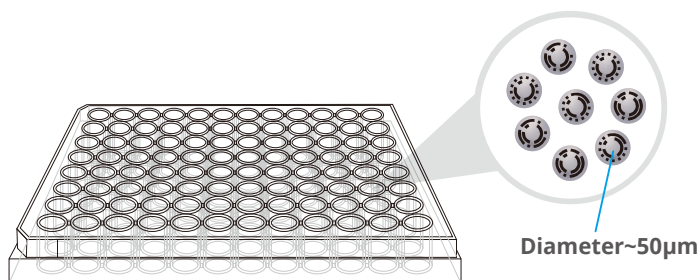


IntelliPlex™ KRAS G12/13 Mutation Kit

The IntelliPlex™ KRAS G12/13 Mutation Kit is a qualitative molecular assay for the detection of somatic mutations on exon 2 of the KRAS gene. A total of 12 mutations can be identified in a single well by using the π Code™ MicroDisc and SelectAmp PCR Technologies. The high sensitivity (down to 0.1%-0.01%) of the IntelliPlex KRAS G12/13 Mutation Kit makes it perfect for liquid biopsy assays.

Single-Well Multiplexing

Multiplexing is made possible by using the π Code MicroDiscs technology. Each probes are individually coated on the MicroDiscs of different image patterns. The coated MicroDiscs are then pooled together for hybridization in a single-well format.



KRAS (12 Mutations)

Exon	A.A Change
Exon 2	G12A, G12D, G12V, G12C, G12R, G12S, G13A, G13D, G13V, G13C, G13R, G13S

▶ PRODUCT HIGHLIGHTS

- Single-well multiplex detection
- Highly sensitivity (0.1% to 0.01%)
- Low sample input (10ng-100ng)
- < 6 hrs turnaround time
(sample preparation included)

▶ INSTRUMENTATIONS

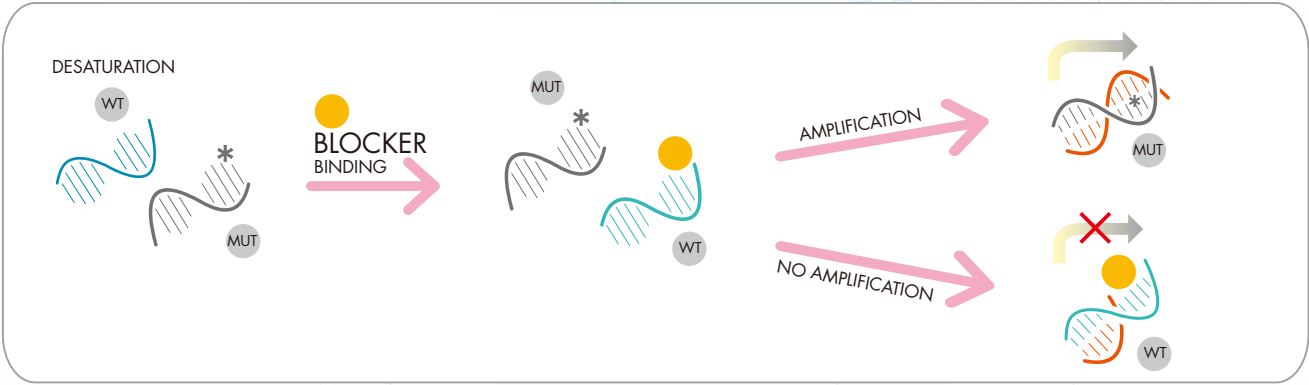
- DigiPlex™ Thermocycler
- IntelliPlex™ 1000 π Code Processor
- PlexBio™ 100 Fluorescent Analyzer

▶ SPECIMEN

- FFPE
- Liquid Biopsy**

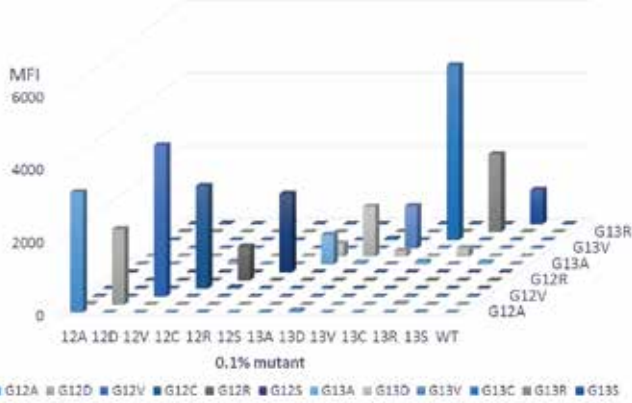
SelectAmp PCR Technology

Selective amplification of mutated gene could be achieved by blocking wild type gene.



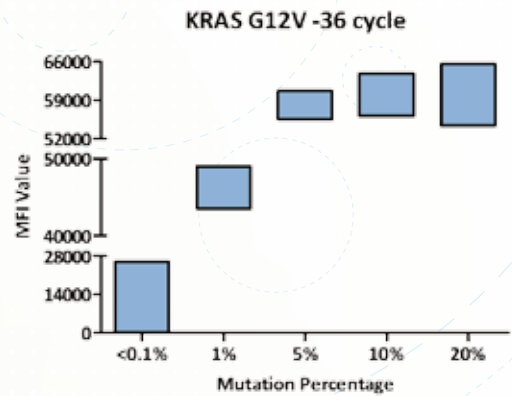
Performance Data

Specificity of KRAS Mutation Assay



The result of specificity shown as above indicates each conjugated probe corresponding to each specific KRAS mutations.

Semi-Quantitative of KRAS Mutation Level in cfDNA



* Higher percentage of mutations can be further distinguished by repeating the assay with fewer, such as 34, amplification cycles.

		Sanger Sequencing			
		Mutation Detected	Mutation Not Detected	Invalid	Total
IntelliPlex KRAS G12/13 Mutation Kit	Mutation Detected	92	17	18	127
	Mutation Not Detected	1	139	15	155
	Invalid	2	17	29	48
	Total	95	173	62	330
Positive agreement = 98.9%					
Negative agreement = 89.1%					
Overall agreement = 92.8%					

Comparison of IntelliPlex KRAS G12/13 Mutation Kit with Sanger Sequencing

	IntelliPlex KRAS G12/13 Mutation Kit *	FDA-approved IVD Kit *
Clinical Sensitivity	98.90%	96.90%
Clinical Specificity	89.10%	88.70%
Overall Agreement	92.80%	91.20%

Comparison of Clinical Sensitivity and Specificity with FDA-approved KRAS Mutation Kit

*Compared with Sanger Sequencing

Order Information

Category	Product Name	Package Volume	Cat. No.
Assay Kit	IntelliPlex™ KRAS G12/13 Mutation Kit	24 rxns	82003

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