

DATA SHEET

hybcell KRAS DNA xA for Patient Stratification



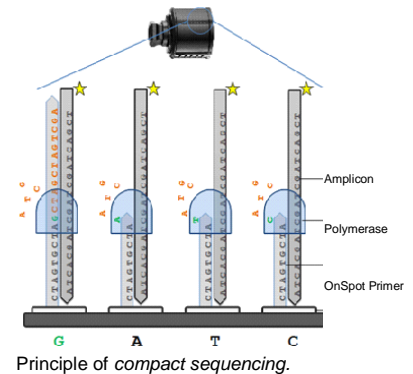
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Multiplexed DNA test for quantitative evidence of 7 clinically relevant point mutations in codons 12/13 of the human KRAS gene.

Benefits

- Few hands-on steps
- Fast (< 2 hours)
- Sensitive (detection limit (LOD) < 1 % mutation vs. wildtype DNA)
- Direct identification of clinically relevant mutations
- Compact sequencing of one to eight samples completely automated
- Cost effective analysis of single samples without reagent wasting



Usage and Product Description

The test is used to establish evidence of seven mutations in codons 12 and 13 of the human KRAS gene. It is based on Cube Dx' compact sequencing technology.

Genomic DNA (15 to 500 ng) isolated from human tumor specimens is amplified in a polymerase chain reaction (PCR) with dye-labelled primers. Amplified and labelled DNA is filled into the hybcell which is analysed in the hyborg device.

Then, single-stranded PCR amplicates hybridize to the immobilized primers, differing in only one base on their 3' end. A highly specific polymerase assures extension only if the last base is complementary to the corresponding base in the amplicate. The hyborg executes primer extension. After stringent washing the remaining fluorescence is measured and raw data are allocated.

After this analysis hyborg creates a clear analysis report.

Several controls ensure proper assay performance. Test duration for one sample (patient) and seven point mutations in KRAS codon 12/13 is approximately 2 hours.

hybcell protocol:	hybcell KRAS DNA xA CE-IVD - A28 - V005	Sample ID	
hybcell ID:	1530A280187	hybcell ID	
Sample ID: ↑#	HTC P1		
hybcell created:	Service, 6/16/2014 10:35:41 AM		
hybcell processed:	Service, 7/25/2013 9:49:52 AM		

Controls	Quality
hybcell	VALID

Criteria	Quality	Visualization
KRAS Codon 12 ... Position 1		
Gly12 Cys (GGT>TGT)	(0 - 5 %) < 5 %	
Gly12 Ser (GGT>AGT)	(0 - 5 %) < 5 %	
Gly12 Arg (GGT>CGT)	(0 - 5 %) < 5 %	
KRAS Codon 12 ... Position 2		
Gly12 Val (GGT>GTT)	(0 - 5 %) < 5 %	
Gly12 Asp (GGT>GAT)	(0 - 5 %) < 5 %	
Gly12 Ala (GGT>GCT)	(0 - 5 %) < 5 %	
KRAS Codon 13 ... Position 2		
Gly13 Asp (GGC>GAC)	(0 - 5 %) 7 %	

Sample volume: 15 to 500 ng of genomic DNA from fresh, fresh frozen or in formalin fixed and in paraffin embedded human tissue

Analysis system: hyborg Dx RED

Test duration for the first sample: about 2 hours (1 h 20 min PCR, 35 min compact sequencing)

Throughput: approx. 6 h 10 min (1 h 20 min PCR plus 4 h 50 min compact sequencing) for an automated analysis of 8 samples

Kit contents: material for 12 tests

Shipping and storage: hybcells can be shipped and stored at room temperature with a shelf life of 24 months. Some components have to be shipped frozen and must be stored at -15 to-25 °C (for maximum 24 months).

Order number: HC0200-12



Specification (*)

No.	Aminoacid change	Base change	Working range
1	Gly12 Cys	GGT > TGT	approx. 5 %
2	Gly12 Ser	GGT > AGT	approx. 5 %
3	Gly12 Arg	GGT > CGT	approx. 5 %
4	Gly12 Val	GGT > GTT	approx. 5 %
5	Gly12 Asp	GGT > GAT	approx. 5 %
6	Gly12 Ala	GGT > GCT	approx. 5 %
7	Gly13 Asp	GGC > GAC	approx. 5 %

(*) As limits of quantification can vary from lot to lot, the lot-specific limits of quantification can be found at our website: www.cubedx.com