

DATA SHEET

hybcell BRAF DNA xA for Patient Stratification



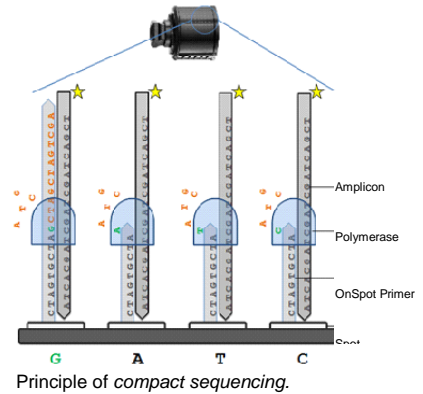
CUBE-DS-15032-V01-E
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Multiplexed DNA test for quantitative evidence of clinically relevant point mutations in codon 600 of the human BRAF gene.

Benefits

- Few hands-on steps
- Fast (< 2 hours)
- Sensitive (detection limit (LOD) of < 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 obtain evidence of BRAF codon 600 mutations in DNA from human tissues. 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 base of 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 the seven point mutations in BRAF codon 600 is approximately 2 hours.

hybcell protocol: hybcell BRAF DNA xA CE-IVD - A18 - V005

hybcell ID: 0000A180000

Sample ID: 1

hybcell created: Service, 6/16/2014 10:34:20 AM

hybcell processed: berronac, 9/7/2012 1:18:44 PM

hybcell approved: not approved

hybcell ID

Controls	Quality
hybcell	VALID

Criteria	Quality	Visualization
BRAF Codon 600 ... Position 1		
Val600Met (GTG>ATG) (0 - 5 %)	< 5 %	
Val600Leu (GTG>CTG) (0 - 5 %)	< 5 %	
Val600Leu (GTG>TTG) (0 - 5 %)	< 5 %	
BRAF Codon 600 ... Position 2		
Val600Glu (GTG>GAG) (0 - 5 %)	23 %	
Val600Ala (GTG>GCG) (0 - 5 %)	< 5 %	
Val600Gly (GTG>GGG) (0 - 5 %)	< 5 %	
BRAF Codon 600 ... Position 1, 2		
Val600Lys (GTG>AAG) (0 - 5 %)	< 5 %	

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: HC0210-12



Specification (*)

No.	Aminoacid change	Base change	Working range
1	Val600Glu	GTG>GAG	approx. 5 %
2	Val600Ala	GTG>GCG	approx. 5 %
3	Val600Gly	GTG>GGG	approx. 5 %
4	Val600Leu	GTG>CTG GTG>TTG	approx. 5 %
5	Val600Met	GTG>ATG	approx. 5 %
6	Val600Lys	GTG>AAG	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