

CERTIFICATE OF ANALYSIS

Product information

Name	Package-Ref™ MRD Cocktail Reference Standard-0.5%
Catalog No.	CBP90040-1
Lot No.	CBFA23050701
Format	ctDNA (ultrasonic treatment)
Buffer	Tris-EDTA
Storage Conditions	-20°C
Date of Manufacture	2023/05/07
Expiry	36 months from the date of manufacture

Quality Control

Test Items	Standard	Results	Passed
Quantity	200.00 ng/vial*1 vial	200.00 ng/vial*1 vial	√
Concentration	20.00 ng/uL±10%	20.00 ng/uL by Qubit 3.0 detection	√
Average Fragmentation Size	160 bp±10%	151.3 bp by Qsep1 detection	√

Sample ID	GENE	Mut.	CDS change	Variant Classification	AF%
MRD-0.5 % ctDNA	EGFR	p.E746_A750delELRE A	c.2236_2250del15 GAATTAAGAGAAGCA>-	Pathogenic	0.69
	EGFR	p.S768I	c.2303G>T	Pathogenic	0.61
	EGFR	p.L861Q	c.2582T>A	Pathogenic	0.61
	ERBB2	p.A775_G776insYVM A	c.2324_2325ins12 ATACGTGATGGC	Pathogenic	0.41
	KRAS	p.G12V	c.35G>T	Pathogenic	0.39
	PIK3CA	p.E542K	c.1624G>A	Pathogenic	0.62
	KRAS	p.Q61H	c.183A>C	Pathogenic	0.49
	EGFR	p.G719C	c.2155G>T	Pathogenic	0.5
	ROS1	CD74-ROS1	chr5:149783684:- (hg19) chr6:117646732:- (hg19)	Pathogenic	0.55
	NRAS	p.Q61K	c.181C>A	Pathogenic	0.41
	IDH1	p.R132C	c.394C>T	Pathogenic	0.43
	FBXW7	p.R505C	c.1513C>T	Pathogenic	0.75
	KMT2C	p.F4496Lfs*21	c.13488delA	Likely Pathogenic	0.46
	RAC1	p.N92I	c.275A>T	Pathogenic	0.4
	BCOR	p.Q1321*	c.3961C>T	Likely Pathogenic	0.68
	BRCA2	p.M784V	c.2350A>G	Benign	0.64
	ARID1A	p.G1848Wfs*6	c.5540dupG	Likely Pathogenic	0.61
	CDH1	p.P126Rfs*89	c.377delC	Pathogenic	0.74
	BARD1	p.K208Rfs*4	c.623delT	Likely Pathogenic	0.38
	BAX	p.E41Rfs*19	c.121delG	Pathogenic	0.75

NBN	p.R466Gfs*18	c.1396delT	Pathogenic	0.71
ARID1B	p.A547Sfs*35	c.1638_1647delGGGCGGC GGC	Pathogenic	0.47
KMT2D	p.Q809Rfs*121	c.2425delG	Likely Pathogenic	0.51
KMT2D	p.P647Hfs*283	c.1940delG	Pathogenic	0.44
QKI	p.K134Rfs*14	c.401delA	Likely Pathogenic	0.63
KMT2B	p.W336*	c.1007G>A	Likely Pathogenic	0.75
NSD1	p.M1531Cfs*43	c.4591delA	Likely Pathogenic	0.74
AXIN1	p.E31*	c.91G>T	Likely Pathogenic	0.66
AXIN1	p.G508Vfs*197	c.91G>T	Likely Pathogenic	0.69
BRAF	p.V600E	c.1799T>A	Pathogenic	5.33
ACVR2A	p.K437Rfs*5	c.1310delA	Likely Pathogenic	3.98
PIK3CA	p.H1047R	c.3140A>G	Pathogenic	2.81
BRCA1	p.D435Y	c.1303G>T	Uncertain significance	2.53
BRCA2	p.N1784Tfs*7	c.5351delA	Pathogenic	2.35
BRCA2	p.E2292A	c.6875A>C	Uncertain significance	1.35
TP53	N/A	c.783-2A>C	Pathogenic	1.02

DdPCR Acceptance criteria

Expected value	Acceptance criteria	Expected value	Acceptance criteria
0%	≤0.1%	<5 copies	Expected value ± 30%
<1%	Expected value ± 50%	≥5 and <10 copies	Expected value ± 20%
≥1% and <5%	Expected value ± 40%	≥10 copies	Expected value ± 15%
≥5% and <10%	Expected value ± 30%		
≥10%	Expected value ± 20%		

Caution:

For research use only.

If you have any questions about the Certificate of Analysis, please contact us.

Certified by:  Date:****

 Date:****