

CERTIFICATE OF ANALYSIS

Product information

Name	Package-Ref™ MRD Cocktail Reference Standard-0.05%
Catalog No.	CBP90040-2
Lot No.	CBFA23050702
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%	162.1 bp by Qsep1 detection	√

Sample ID	GENE	Mut.	CDS change	Variant Classification	AF%
MRD-0.05 % ctDNA	BRAF	p.V600E	c.1799T>A	Pathogenic	0.54
	ACVR2A	p.K437Rfs*5	c.1310delA	Likely Pathogenic	0.40
	PIK3CA	p.H1047R	c.3140A>G	Pathogenic	0.26
	BRCA1	p.D435Y	c.1303G>T	Uncertain significance	0.24
	BRCA2	p.N1784Tfs*7	c.5351delA	Pathogenic	0.23
	BRCA2	p.E2292A	c.6875A>C	Uncertain significance	0.14
	TP53	N/A	c.783-2A>C	Pathogenic	0.11

The %AF of mutations were used to check the dilution-fold from 0.5% to 0.05%

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:****