

CERTIFICATE OF ANALYSIS

Product information

Name	Package-Ref™ MRD Cocktail Reference Standard-0.005%
Catalog No.	CBP90040-3
Lot No.	CBFA23050703
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%	163.2 bp by Qsep1 detection	√

Sample ID	GENE	Mut.	CDS change	Variant Classification	AF%
MRD-0.00	BRAF	p.V600E	c.1799T>A	Pathogenic	0.047
5% ctDNA	ACVR2A	p.K437Rfs*5	c.1310delA	Likely Pathogenic	0.038

The %AF of mutations were used to check the dilution-fold from 0.05% to 0.005%

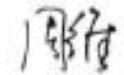
DdPCR Acceptance criteria

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:****