

CERTIFICATE OF ANALYSIS

General information

Name	Panel-Ref® Structural Variation Cocktail I-ctDNA
Catalog No.	CBP90034
Lot No.	CBFA23090408
Format	ctDNA (ultrasonic treatment)
Buffer	Tris-EDTA
Storage Conditions	-20°C
Date of Manufacture	2023/09/04
Expiry	36 months from the date of manufacture

Quality Control

Test Items	Standard	Results	Passed
Quantity	1.00 µg/vial *1 vial	1.00 µg/vial *1 vial	√
Concentration	20.00 µg/uL±10%	20.00 µg/uL by Qubit 3.0 detection	√
Average Fragmentation Size	160 bp±10%	170.2 bp by Qsep1 detection	√

Gene	DNA Change	AA Change	Variant Type	%AF
AKT1	c.49G>A	p.E17K	SNV	5.43%
PIK3CA	c.1624G>A	p.E542K	SNV	4.88%
ERBB2	c.2324_2325ins12	p.A775_G776insYVMA	Insertion	4.56%
EGFR	c.2235_2249del15	p.E746_A750delELREA	Deletion	5.32%
ROS1	N/A	CD74(E6)-ROS1(E34) Fusion	Fusion	4.25%
ALK	N/A	EML4(E13)-ALK(A20) Fusion V1	Fusion	4.13%
MET	N/A	MET Amplification	CNV	CN=4.72
ERBB2	N/A	ERBB2 Amplification	CNV	CN=5.00
NRAS	c.181C>A	p.Q61K	SNV	4.52%
IDH1	c.394C>T	p.R132C	SNV	4.29%

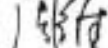
DdPCR Acceptance criteria

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