

Certificate of Analysis

For Research Use Only
Not for Use in Diagnostic Procedures

Product Description: Seraseq™ Tri-Level Tumor Mutation DNA Mix v2, RUO
 Material Number: 0710-0097 Batch Number: 10551335
 Volume: 25 µL Concentration: 25 ng/µL
 Date of Manufacture: 12 FEB 2021 Expiration Date: 12 FEB 2023

Test Method for Concentration: Qubit dsDNA BR Assay
 Average Concentration (ng/µL): 25 ng/µL
 Test Method for Variant Allele Frequency: In house validated, allele specific, digital PCR assays

4% Tier	
Mutation	Avg. dPCR Allele Frequency
BRAF COSM476	4.1
EGFR COSM12378	3.7
EGFR COSM6225	3.9
EGFR COSM6240	3.7
FGFR3 COSM715	4.0
FLT3 COSM783	3.5
FOXL2 COSM33661	3.7
IDH1 COSM28747	3.4
PDGFRA COSM28053	3.4
PIK3CA COSM775	3.5
PIK3CA COSM12464	3.6
RET COSM965	3.4
TP53 COSM18610	N/A

10% Tier	
Mutation	Average dPCR Allele Frequency
AKT1 COSM33765	9.5
APC COSM13127	10.3
APC COSM18561	9.5
ATM COSM21924	9.8
ERBB2 COSM682	8.8
GNA11 COSM52969	10.4
GNAQ COSM28758	9.8
KIT COSM1314	9.7
MPL COSM18918	10.5
NCOA4-RET	9.4
PDGFRA COSM736	10.9
PIK3CA COSM763	9.8
SMAD4 COSM14105	9.0
TPR-ALK	9.5

7% Tier	
Mutation	Average dPCR Allele Frequency
CTNNB COSM5664	8.2
EGFR COSM6224	5.9
GNAS COSM27887	6.0
JAK2 COSM12600	6.8
KRAS COSM521	7.9
NPM1 COSM17559	6.1
NRAS COSM584	6.1
PTEN COSM4986	6.0
PTEN COSM5809	6.0
TP53 COSM10648	5.7
TP53 COSM6530	5.7
TP53 COSM10662	5.7
TP53 COSM10660	5.4

Approval:

Prepared By

Date

QA Verified By

Date




21 APR 2021

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