LUCENCE

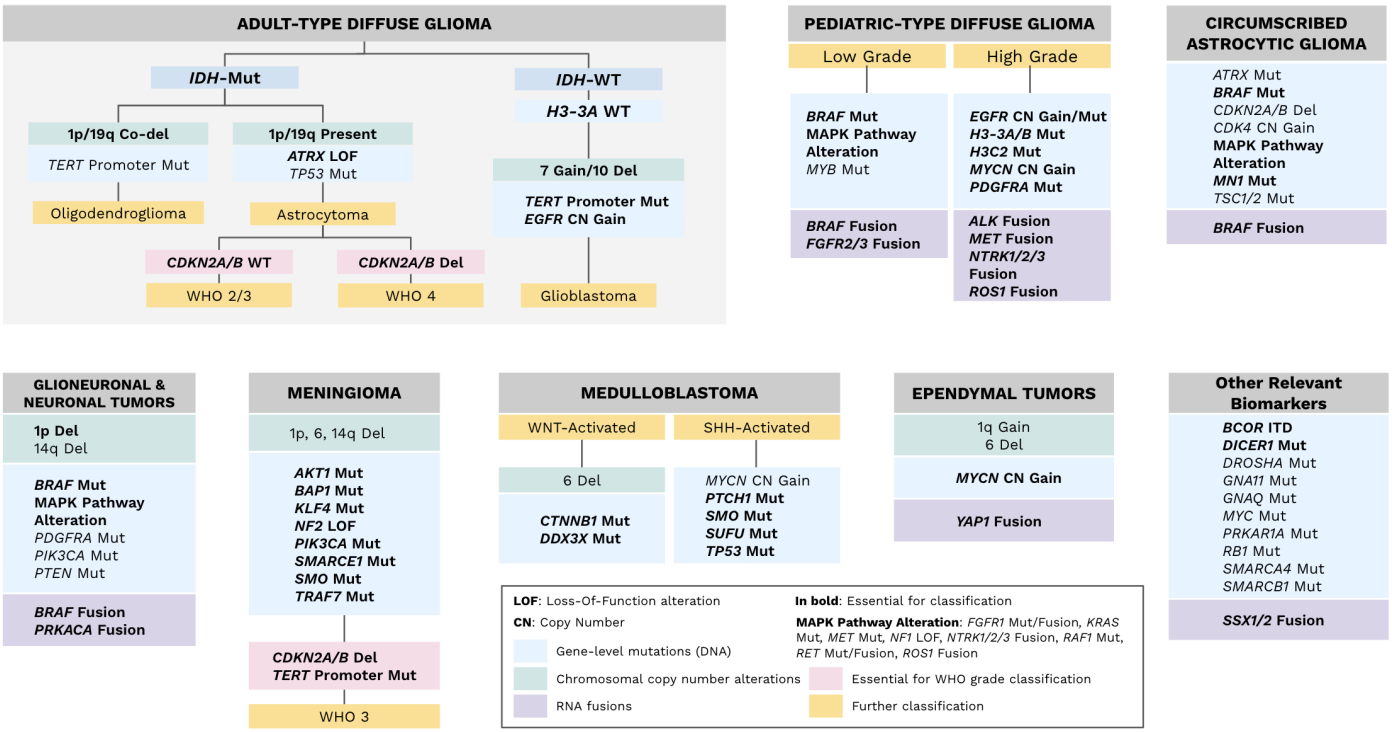
Profiling Brain Tumors to Standard-of-Care

Supporting WHO Blue Book CNS Tumor Classification [1]

UNITED™ CNS is a next-generation sequencing (NGS) panel aiding in the classification of central nervous system (CNS) tumors.

The test runs simultaneous interrogation of molecular alterations essential for the classification of various CNS tumor subtypes and grades — supporting accurate diagnosis and treatment of both adult and pediatric CNS tumors.

WHO 2021 CNS Tumor Classification - Required Targets on UNITED™ CNS



Test Specifications [2]

Methodology	Ultra-deep next-generation sequencing
Biomarkers analyzed	• SNVs, Indels, Fusions • Gene copy number variations, chromosomal copy number alterations • Microsatellite Instability (MSI) and Tumor Mutational Burden (TMB)
Sample type	FFPE tumor tissue
Turnaround time	2 weeks

	Sensitivity	Specificity
SNVs/Indels	98%	100%
Fusions	91.25%	100%
MSI-High	100%	100%

	R^2 Correlation to Whole Exome Sequencing
TMB	98.6%

- Results tested at the stated mutant allele frequencies using reference standards, FFPE cell line samples, and FFPE clinical samples.
- Sensitivity and specificity reported for SNVs and Indels are at 5% VAF.
- The limit of detection for chromosomal copy number alterations is 30% tumor fraction.

References [1] Gritsch, S. et al. Cancer 2022 128(1):47–58. [2] Ng, CC-Y. et al. Front. Mol. Biosci. 2022. 9:963243.

Gene List

The subset of genes relevant to CNS, targeted by UNITED™ CNS. Full gene list in UNITED™ brochure.

SNVs, Indels & CNVs

AKT1	***CDKN2A***	***FGFR1***	***H3C2***	*MYB*	***NTRK3***	*RB1*	***SSX1***
ALK	***CDKN2B***	***FGFR2***	***IDH1***	*MYC*	***PDGFRA***	***RET***	***SUFU***
ATRX	***CTNNB1***	***FGFR3***	***IDH2***	***MYCN***	*PIK3CA*	***ROS1***	***TERT***
BAP1	***DDX3X***	*GNA11*	*KLF4*	***NF1***	***PRKAR1A***	*SMARCA4*	***TP53***
BCOR	***DICER1***	*GNAQ*	***KRAS***	***NF2***	***PTCH1***	*SMARCB1*	*TRAF7*
BRAF	*DROSHA*	***H3-3A***	***MET***	***NTRK1***	*PTEN*	***SMARCE1***	*TSC1*
CDK4	***EGFR***	***H3-3B***	***MN1***	***NTRK2***	***RAF1***	***SMO***	*TSC2*

Genes in **bold** are essential for standard-of-care CNS classification.

RNA Fusions

ALK	*FGFR1*	***MET***	***NTRK2***	*PDGFRA*	*RAF1*	***ROS1***	***SSX2****
BRAF	***FGFR2***	***NTRK1***	***NTRK3***	***PRKACA****	*RET*	***SSX1***	***YAP1****
EGFR	***FGFR3***						

Genes in **bold** are essential for standard-of-care CNS classification.
***Genes tested in RNA panel only.**

Chromosomal Copy Number Alterations

1p	1q	6	**7**	**10**	14q	19p	**19q**

Chromosome/chromosome arms in **bold** are essential for standard-of-care CNS classification.

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