

Ascent™ Report

Patient Information	Provisional Diagnosis	Specimen	Physician Information
Name: Jane Doe DOB: 01/01/1990 Sex Assigned at Birth: Female MRN: 11xx22xx33	Diagnosis: Metastatic Breast Carcinoma; Central Nervous System Neoplasm ICD10: C79.32	Type: CSF Collected: 01/01/2026 Received: 01/02/2026 Specimen ID: AscOnlyNeg-Mets	Institution: Belay Diagnostics Referring Physician: Provider Test

RESULT SUMMARY

NEGATIVE

Comments
The absence of a clinically significant finding in this report does not necessarily indicate the absence of chromosomal alterations in this specimen that could be present below the limit of detection of the test or affect the X or Y chromosomes which are not evaluated by Ascent™. Clinical correlation is required.

CLINICALLY SIGNIFICANT ALTERATION DETAILS (Tier 1 or 2 per AMP/ASCO/CAP)

Ascent™ Chromosome Arm Level Loss or Gain: None

VARIANTS OF UNKNOWN SIGNIFICANCE (Tier 3)

None

ACTIONABILITY SUMMARY

None

CLINICAL TRIALS / INVESTIGATIONAL THERAPIES

None

TIER 1A THERAPY DETAILS

None

TEST DETAILS

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Aneuploidy (chromosome arm level loss and gain)									
chr1p	chr3p	chr5p	chr7p	chr9p	chr11p	chr13q	chr16q	chr18q	chr20q
chr1q	chr3q	chr5q	chr7q	chr9q	chr11q	chr14q	chr17p	chr19p	chr21q
chr2p	chr4p	chr6p	chr8p	chr10p	chr12p	chr15q	chr17q	chr19q	chr22q
chr2q	chr4q	chr6q	chr8q	chr10q	chr12q	chr16p	chr18p	chr20p	

Methods and Limitations

Ascent™ evaluates chromosomal arm level loss/gain (aneuploidy), and focal alterations (gene level amplification/deletion) using >0.1x low pass whole genome sequencing (LP-WGS) (PMID: 37014860). The LOD (limit of detection) for aneuploidy was determined to be $\log_2(r)$ of abs (0.09), and for focal alteration was determined to be seq.mean cutoff of 0.1 for amplification and -0.2 for deletions. Variants are called against the human genome build reference hg19 using Summit™ Omics pipeline version 1.3.0, developed at Belay Diagnostics.

Tertiary analysis is performed using the precision oncology workbench (GenomOncology) based on the joint AMP/ASCO/CAP consensus guidelines for interpretation of sequence variants in cancer (PMID: 27993330). Please reach out to contact@belaydiagnostics.com for additional information or queries.

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Disclaimers

This test was developed, and its performance characteristics determined by Belay Diagnostics Laboratory (CLIA# 14D2302605), which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity testing. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). This test may be used for clinical purposes. However, the results of this test do not establish a diagnosis and should not be used alone for diagnosis or patient care decisions or otherwise replace the judgment of a treating physician and must always be interpreted in the context of all relevant clinical and pathological data.

This test is performed only to evaluate for somatic (i.e., tumor-specific) variants within the genes listed and cannot distinguish between germline and somatic alterations with absolute certainty. This test therefore does not report on incidental findings as defined by the American College for Medical Genetics and Genomics (ACMG) (PMID: 37347242). If a germline variant is suspected, follow-up germline testing using non-neoplastic (normal) tissue should be performed by a laboratory permitted to perform germline genetic testing along with genetic counseling. It is possible for a genomic variant to be present yet go undetected by our assay either due to the heterogeneous nature of the specimen or the limits of detection of our assay. Therefore, to the extent a particular genomic variant is not reported, Belay Diagnostics LLC does not guarantee that the variant does not exist in the specimen provided. Likely benign, and benign variants are not reported. For any reported variant of uncertain significance (VUS), if the classification changes, there is no obligation to send out a new report updating this information.

The information presented in the clinical trials and therapeutic sections of this report is compiled from public sources which are continuously updated. While we strive to ensure this information is accurate and complete, we cannot guarantee the accuracy or completeness of this information. This public sourced information is not ranked in order of potential or predicted efficacy and may not be complete. Specific eligibility criteria should be reviewed as applicable. This information may include associations between a genomic variant (or lack of a variant) and one or more therapeutic agents with potential clinical benefit (or lack of clinical benefit), including agents that are being studied in clinical research. The finding of a genomic variant does not necessarily indicate or demonstrate pharmacologic effectiveness (or lack thereof) of any agent or treatment regimen found in public source information. Similarly, the finding of "no clinically significant variant" does not necessarily indicate or demonstrate lack of pharmacologic effectiveness (or lack of effectiveness) of any agent or treatment regimen found in public source information. Belay Diagnostics expressly disclaims, and makes no representation of or warranty of, the accuracy or completeness with respect to the publicly available information included herein or reviewed or collected during creation of this report.

ACTIONABILITY REFERENCES

FDA: U.S. Food & Drug Administration (fda.gov)

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WHO: World Health Organization Classification of Tumours online (tumourclassification.iarc.who.int)

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