BELAY DIAGNOSTICS

Date: 11/10/2026
Order ID: SumAsc-Pos-Breast-ERBB2

1375 W. Fulton Street, Suite 530
Chicago, IL 60607
Email: contact@belaydiagnostics.com
Phone: (331) 320-0155 | Fax: (800) 501-9246

Summit™ 2.0 + 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 **CSF Volume Received:**6 mL	**Type:**CSF **Collected:**11/03/2026 **Received:**11/04/2026 **Specimen ID:**SumAsc-Pos-Breast-ERBB2	**Institution:**Belay Diagnostics **Referring Physician:**Provider Test

RESULT SUMMARY

CLINICALLY SIGNIFICANT VARIANTS - DETECTED

Comments

ERBB2 (HER2) amplification is a predictive diagnostic and therapeutic marker for central nervous system metastases from breast carcinoma (see Actionability Summary, PMID: 23204226). *PIK3CA* activating alterations and *CDH1* truncating variants are also frequent findings in breast cancer metastasis (PMID: 40142329, 25473901, 2070412, 9515965, 31481116). Clinical correlation is required.

While most chromosomal arm-level alterations are considered variants of unknown significance (VUS) on their own, a high level of chromosomal loss and gain as observed in this specimen indicates chromosomal instability, a key driver of metastasis across cancer types (PMID: 38924459). Clinical correlation is required.

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

Summit™ 2.0 - SNV, MNV, Indel Variants

Alteration	VAF	Actionability Summary		
		FDA/NCCN Therapies Associated	Prognostic/Diagnostic Guidelines	Clinical Trial Options
CDH1 p.G62fs c.183del	21.2%	No	Yes	No
PIK3CA p.E542K c.1624G>A	1.5%	No	No	Yes

Summit™ 2.0 - Copy Number Variants

Alteration	Location	Fold Change	Actionability Summary		
			FDA/NCCN Therapies Associated	Prognostic/Diagnostic Guidelines	Clinical Trial Options
ERBB2 Amplification	chr17	6.41	Yes	No	Yes

Summit™ 2.0 - Fusion Variants

None

Summit™ 2.0 - Biomarkers

Tumor Mutation Burden (TMB)			Microsatellite Instability (MSI)	
Not Detected	Low	High	Stable	High

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Ascent™ - Chromosome Arm Level Loss or Gain
None

VARIANTS OF UNKNOWN SIGNIFICANCE (Tier 3)

Summit™ 2.0 - SNV/MNVs/Indels				
AR I836M	*DNMT3A* R729W	*H3C6* Q77E	*MAP3K14* R218Q	*RECQL4* G870E
ARID1B Q1349del	*ERBB2* D1125E	*IRS2* A624G	*MCL1* L144P	*RNF43* Q588*
ASXL2 V236D	*FANCC* Q283E	*KDR* A757G	*PBRM1* E903Q	*SLX4* H1353N
CYLD S246C	*FOXP1* c.1531-1G>A	*MAP3K14* R218fs	*PIK3R3* L421P	*TMPRSS2* R526=

Summit™ 2.0 - Gene Level CNVs
None

Summit™ 2.0 - Fusions
None

Ascent™ - Aneuploidy Variants of Unknown Significance			
chr1p Loss	chr5q Gain	chr12p Loss	chr18q Loss
chr1q Gain	chr11p Loss	chr13q Loss	chr22q Gain
chr5p Gain	chr11q Loss	chr16q Loss	

ACTIONABILITY SUMMARY

FDA / NCCN Therapies for the Patient's Tumor Type (Tier 1A)

Biomarker	Therapies	Setting	Source(s)
ERBB2 Amplification	fam-trastuzumab deruxtecan + pertuzumab; pertuzumab + trastuzumab +/- (paclitaxel or docetaxel)	First line	FDA (Approved), NCCN
ERBB2 Amplification	ado-trastuzumab emtansine; pertuzumab/trastuzumab/hyaluronidase; trastuzumab +/- chemotherapy; trastuzumab/hyaluronidase	Metastatic	FDA (Approved), NCCN
ERBB2 Amplification	fam-trastuzumab deruxtecan	Unresectable or metastatic	FDA (Approved), NCCN
ERBB2 Amplification	lapatinib + capecitabine; margetuximab + chemotherapy; neratinib + capecitabine; trastuzumab + tucatinib + capecitabine	Subsequent line	FDA (Approved), NCCN
ERBB2 Amplification	pertuzumab + trastuzumab + tucatinib	Maintenance	FDA (Approved)
ERBB2 Amplification	lapatinib + trastuzumab	Metastatic	NCCN

FDA / NCCN Therapies with Resistance / Decreased Response (Tier 1A)
None

Prognostic Implications per NCCN
None

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Diagnostic Implications per WHO		
Biomarker	**Diseases**	**Note**
CDH1 G62fs	Breast Neoplasm	In breast invasive lobular carcinoma, mutations of CDH1 are frequent (50-80%), and CDH1 mutation is also identified in 81% of lobular carcinoma in situ cases. CDH1 inactivation, which leads to loss or impaired function of E-cadherin, is an early event and hallmark of lobular breast lesions (PMID: 9365159). E-cadherin mediates cell-cell adhesion and plays a key role in the maintenance of lobular architecture. It can also inhibit the growth and invasion of breast cancer cells (PMID: 11597316; PMID: 21346732). Defective E-cadherin results in loss of cell-cell adhesion, increased cell proliferation, and altered organization of the lobules, giving rise to the characteristic appearance of lobular neoplasia (PMID: 21282721; PMID: 17097565). Additionally, several CDH1 germline alterations have been reported to be associated with an increased risk of lobular breast carcinoma.

CLINICAL TRIALS / INVESTIGATIONAL THERAPIES

***ERBB2* Amplification**			
Therapy	**Clinical Trial**	**Location/Sponsor**	**Quick Access**
GLSI-100	NCT05232916 (Phase 3) Phase 3 Study to Evaluate the Efficacy and Safety of HER2 /Neu Peptide GLSI-100 (GP2 + GM-CSF) in HER2/Neu Positive Subjects	Goodyear, Arizona Greenwich LifeSciences, Inc. Jaye.Thompson@GreenwichLifeSciences.com	https://genomoncology.wetrials.com/v1/NCT05232916
carvedilol	NCT03418961 (Phase 3) S1501 Dual Observational and Randomized Cohort Study of Patients With Metastatic HER-2+ Breast Cancer at Risk of Cardiac Toxicity	Baton Rouge, Louisiana SWOG Cancer Research Network	https://genomoncology.wetrials.com/v1/NCT03418961
trastuzumab + liposomal doxorubicin + paclitaxel	NCT00294996 (Phase 3) Trial of Myocet in Metastatic Breast Cancer	San Diego, California Sopherion Therapeutics	https://genomoncology.wetrials.com/v1/NCT00294996
zanidatamab + (capecitabine or eribulin or gemcitabine or vinorelbine)	NCT06435429 (Phase 3) A Study Comparing the Efficacy and Safety of Zanidatamab to Trastuzumab, Each in Combination With Physician's Choice Chemotherapy, for the Treatment of Participants With Metastatic HER2-positive Breast Cancer	Phoenix, Arizona Jazz Pharmaceuticals ClinicalTrialDisclosure@JazzPharma.com	https://genomoncology.wetrials.com/v1/NCT06435429

***ERBB2* Amplification + *PIK3CA* E542K**			
Therapy	**Clinical Trial**	**Location/Sponsor**	**Quick Access**
inavolisib + pertuzumab/trastuzumab /hyaluronidase + taxane +/- hormone therapy	NCT05894239 (Phase 3) A Study to Evaluate the Efficacy and Safety of Inavolisib in Combination With Phesgo Versus Placebo in Combination With Phesgo in Participants With PIK3CA-Mutated HER2-Positive Locally Advanced or Metastatic Breast Cancer	Gilbert, Arizona Hoffmann-La Roche global-roche-genentech-trials@gene.com	https://genomoncology.wetrials.com/v1/NCT05894239

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PIK3CA E542K			
Therapy	**Clinical Trial**	**Location/Sponsor**	**Quick Access**
AMXT-1501 + capivasertib + eflornithine + fulvestrant	NCT07287917 (Phase 1/Phase 2) Study of AMXT 1501 and DFMO in Combination With Standard Therapies in Advanced Solid Tumors	Tucson, Arizona Aminex Therapeutics, Inc. mburns@aminextx.com	https://genomoncology.wetrials.com/v1/NCT07287917
TER-2013	NCT07109726 (Phase 1/Phase 2) A Phase 1/2 Trial of TER-2013 in Patients With Solid Tumors Harboring AKT/PI3K/PTEN Pathway Alterations	Duarte, California Terremoto Biosciences Inc. clinicaltrials@terremotobio.com	https://genomoncology.wetrials.com/v1/NCT07109726
alpelisib + fulvestrant + dapagliflozin	NCT05025735 (Phase 2) Alpelisib, Fulvestrant and Dapagliflozin for the Treatment of HR+, HER2 -, PIK3CA Mutant Metastatic Breast Cancer	Kansas City, Missouri Saint Luke's Health System slci1research@saint-lukes.org	https://genomoncology.wetrials.com/v1/NCT05025735
tersolisib	NCT05768139 (Phase 1/Phase 2) First-in-Human Study of Tersolisib (STX-478) as Monotherapy and in Combination With Other Antineoplastic Agents in Participants With Advanced Solid Tumors	Los Angeles, California Eli Lilly and Company LillyTrials@Lilly.com	https://genomoncology.wetrials.com/v1/NCT05768139

TIER 1A THERAPY DETAILS

ERBB2 Amplification		
Therapy	**Approval / Guideline Summary**	**Underlying Evidence**
ado-trastuzumab emtansine	FDA approved for HER2-positive, metastatic breast cancer that previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for metastatic disease, or developed disease recurrence during or within six months of completing adjuvant therapy. NCCN recommended as Category 2A.	In a Phase III trial (EMILIA) that supported FDA approval, treatment with Kadclya (trastuzumab emtansine) improved median progression free survival (9.6 mo vs 6.4 mo) and overall survival (30.9 mo vs 25.1 mo) compared to Tykerb (lapatinib) combined with Xeloda (capecitabine) in patients with metastatic ERBB2 (HER2)-positive breast cancer (PMID: 24879797, PMID: 23020162; NCT00829166). In a Phase II (MATCH) trial, Kadcyla (trastuzumab emtansine) treatment resulted in partial response in 8.1% (3/37) and stable disease in 43% (16/37) of patients with ERBB2 (HER2) amplified non-breast, non-gastric advanced solid tumors, with a 6-month progression-free survival rate of 24.8% (J Clin Oncol 36, 2018 (suppl; abstr 100); NCT02465060).
fam-trastuzumab deruxtecan	FDA approved for adults with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen either in the metastatic setting, or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within 6 months of completing therapy. NCCN recommended for subsequent line or first line therapy (Category 1/Preferred intervention).	The FDA approval for fam-trastuzumab deruxtecan was supported by data from the open-label, randomized, phase-III trial DESTINY-Breast03 (NCT03529110). DESTINY-Breast03 demonstrated that subsequent-line fam-trastuzumab deruxtecan, compared with ado-trastuzumab emtansine, improved median PFS (HR = 0.28, p < 0.0001; NR (n = 261) vs. 6.8 mo. (n = 263)) in patients with metastatic or unresectable, HER2+ breast carcinoma. The secondary endpoint was ORR (82.7% vs. 36.1%). The FDA approval for fam-trastuzumab deruxtecan was also supported by data from the single-arm, phase-II trial DESTINY-Breast01 (NCT03248492; PMID: 31825192). DESTINY-Breast01 demonstrated that subsequent-line fam-trastuzumab deruxtecan

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		had an ORR of 60.3% (n = 184; CR, 4.3%; PR, 56.0%) and a median DOR of 14.8 mo. (n = 184) in patients with metastatic or unresectable, HER2+ breast carcinoma.
fam-trastuzumab deruxtecan + pertuzumab	FDA approved as first line therapy for adults with unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast carcinoma. NCCN recommended as Category 2A/Other recommended intervention.	The FDA approval for fam-trastuzumab deruxtecan + pertuzumab was supported by data from the randomized, three-arm, multicenter, phase-III trial DESTINY-Breast09 (NCT04784715). DESTINY-Breast09 demonstrated that first line fam-trastuzumab deruxtecan + pertuzumab (n = 383), compared to taxane + [docetaxel or paclitaxel] + fam-trastuzumab deruxtecan + pertuzumab (n = 387) improved median PFS (40.7 mo. vs. 26.9 mo., HR = 0.56; p < 0.0001) in patients with HER2 positive unresectable or metastatic breast carcinoma. Additional endpoint was ORR (87% vs. 81%).
lapatinib + capecitabine	FDA approved for advanced or metastatic breast cancer that overexpresses HER2 and that had prior therapy including an anthracycline, a taxane, and trastuzumab. NCCN recommended as Category 2A.	The FDA approval for lapatinib + capecitabine was supported by data from the randomized, phase-III trial NCT00078572 (PMID: 17192538). NCT00078572 demonstrated that subsequent-line lapatinib + capecitabine, compared with capecitabine, improved median time to progression (HR = 0.57; p = 0.00013; 27.1 weeks vs. 18.6 weeks) in patients with locally advanced or metastatic, HER2-Positive BCa. The secondary endpoint was median OS (75.0 weeks vs. 65.9 weeks).
lapatinib + trastuzumab	NCCN recommended as subsequent line therapy for unresectable, recurrent, or metastatic HER2-positive breast cancer, without cytotoxic therapy (Category 2A).	
margetuximab + chemotherapy	FDA approved for metastatic HER2-positive breast cancer that received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. NCCN recommended as Category 2A.	In a Phase III trial (SOPHIA) that supported FDA approval, Margenza (margetuximab-cmkb) in combination with chemotherapy resulted in improved primary progression-free survival (5.8 vs 4.9 mo, HR=0.76, p=0.03) compared to Herceptin (trastuzumab) plus chemotherapy in patients with ERBB2 (HER2)-positive (IHC 3+ or FISH amplified) metastatic breast cancer whose disease progressed after two or more lines of anti-ERBB2 (HER2) therapies (PMID: 33480963; NCT02492711).
neratinib + capecitabine	FDA approved for advanced or metastatic HER2-positive breast cancer that had two or more prior anti-HER2 based regimens in the metastatic setting. NCCN recommended as Category 2A.	In a Phase III (NALA) trial that supported FDA approval, combination of Nerlynx (neratinib) and Xeloda (capecitabine) reduced risk of disease progression or death (HR=0.76, p=0.006), improved 12-month PFS (28.8%, 88 /307 vs 14.8%, 46/314) compared to lapatinib and capecitabine combination in patients with metastatic ERBB2 (HER2)-positive (amp/over exp) breast cancer who had 2 or more prior ERBB2 (HER2)-targeted therapies (J Clin Oncol 37, no. 15_suppl (May 20, 2019) 1002-1002; NCT01808573).
pertuzumab + trastuzumab + tucatinib	FDA approved as maintenance therapy for adults with unresectable locally advanced or metastatic HER2-positive breast cancer following induction treatment.	The FDA approval for tucatinib + trastuzumab + pertuzumab was supported by data from the randomized, double-blind, placebo-controlled, phase-III trial HER2CLIMB-05 (NCT05132582). HER2CLIMB-05 demonstrated that maintenance tucatinib + trastuzumab + pertuzumab (n = 326), compared to placebo + trastuzumab + pertuzumab (n = 328), improved median PFS (24.9 mo. vs. 16.3 mo., HR = 0.64; p < 0.0001) in patients with HER2-positive unresectable locally advanced or metastatic breast carcinoma following induction treatment. Additional endpoint included OS (immature at the time of the PFS analysis with 8% of deaths across both arms).
pertuzumab + trastuzumab +/- (paclitaxel or docetaxel)	FDA approved with paclitaxel for HER2-positive metastatic breast cancer that has not received prior anti-HER2 therapy or chemotherapy for metastatic disease. NCCN recommended as a Preferred intervention (Category 1 for docetaxel, Category 2A for paclitaxel). Per NCCN, may also be considered if previously treated with trastuzumab plus chemotherapy in the absence of pertuzumab.	The FDA approval for pertuzumab + trastuzumab +/- (docetaxel or paclitaxel) was supported by data from the double-blind, placebo-controlled, phase-III trial CLEOPATRA (NCT00567190; PMID: 22149875). CLEOPATRA demonstrated that first-line pertuzumab + trastuzumab + docetaxel, compared with placebo + trastuzumab + docetaxel, improved median PFS (HR = 0.62; p < 0.0001; 18.5 mo. vs. 12.4 mo.; no. of events, 47.5% (191/402) vs. 59.6% (242/406)) in patients with metastatic, HER2-Positive BCa. Secondary endpoints were OS (HR = 0.68), ORR (80.2% (275/343) vs. 69.3% (233/336)) and median DOR (20.2 mo. vs. 12.5 mo.).
pertuzumab/trastuzumab /hyaluronidase	FDA approved with paclitaxel for HER2-positive metastatic breast cancer that has not received prior anti-HER2 therapy or chemotherapy for metastatic disease. Per NCCN, pertuzumab/trastuzumab/hyaluronidase injection for subcutaneous use may be substituted anywhere that the combination of intravenous pertuzumab and intravenous trastuzumab are given as part of systemic therapy.	In a Phase III trial (FeDeriCa) that supported FDA approval, Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf) demonstrated pharmacokinetics, safety, and efficacy comparable to i.v. pertuzumab and trastuzumab (H+P) (Cancer Res 2020;80(4 Suppl):Abstract nr PD4-07; NCT03493854), warranted the extrapolation of data from a Phase III trial supporting the approval of H+P plus docetaxel in Erbb2 (Her2)-positive metastatic breast cancer (PMID: 23602601; NCT00567190) for approval of Phesgo (FDA.gov).
trastuzumab + tucatinib + capecitabine	FDA approved for advanced unresectable or metastatic HER2-positive breast cancer, including brain metastases, that had one or more prior anti-HER2-based regimens in the metastatic setting. NCCN recommended as Category 1 /Preferred intervention.	In a Phase II trial (HER2CLIMB) that supported FDA approval, addition of Tukysa (tucatinib) to Herceptin (trastuzumab) and Xeloda (capecitabine) significantly improved progression-free survival at 1 year (PFS1) compared to placebo (33.1% vs 12.3%, HR=0.54, p<0.001) in patients with metastatic ERBB2 (HER2)-positive breast cancer who received prior HER2-targeted therapy, PFS1 was significantly improved (24.9% vs 0%, HR=0.48, p<0.001) in patients with brain metastasis (PMID: 31825569; NCT02614794).

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trastuzumab +/- chemotherapy	FDA approved for HER2-overexpressing metastatic breast cancer, with paclitaxel as first-line treatment, and as a single agent after one or more chemotherapy regimens. NCCN recommended with various chemotherapy options as Category 2A.	The FDA approval for trastuzumab +/- chemotherapy was supported by two trials: Study 5 (PMID:11248153) and Study 6. Data from the open-label, randomized, phase-III trial Study 5 demonstrated that first-line trastuzumab + chemotherapy, compared with chemotherapy, improved median time to progression (p < 0.0001; 7.2 mo. vs. 4.5 mo.) in patients with metastatic, HER2-Positive BCa. Secondary endpoints were ORR (45% vs. 29%), median DOR (8.3 mo. vs 5.8. mo.), and median OS (25.1 mo. vs. 20.3 mo.). Data from the open-label, single-arm, phase-II trial Study 6 demonstrated that subsequent-line trastuzumab conferred an ORR of 14 % (CR, 2%; PR, 12%) in patients with metastatic, HER2-Positive BCa.
trastuzumab/hyaluronidase	FDA approved for HER2-overexpressing metastatic breast cancer, with paclitaxel as first-line treatment, and as a single agent after one or more chemotherapy regimens. Per NCCN, trastuzumab/hyaluronidase injection for subcutaneous use may be substituted for trastuzumab in any regimen.	The FDA approval for trastuzumab/hyaluronidase +/- chemotherapy was supported by two trials: H0648g (PMID: 11248153) and H0649g. Data from the open-label, randomized, phase-III trial H0648g demonstrated that first-line trastuzumab + chemotherapy, compared with chemotherapy, improved median time to progression (p < 0.0001; 7.2 mo. vs. 4.5 mo.) in patients with metastatic, HER2-Positive BCa. Secondary endpoints were ORR (45% vs. 29%), median DOR (8.3 mo. vs 5.8. mo.), and median OS (25.1 mo. vs. 20.3 mo.). Data from the open-label, single arm phase-II trial H0649g demonstrated that subsequent-line trastuzumab conferred an ORR of 14 % (CR, 2%; PR, 12%) in patients with metastatic, HER2-Positive BCa.

TEST DETAILS

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PANEL CONTENT AND REPORTING TRANSCRIPTS

ABL1 NM_005157.4^
ABL2 NM_007314.3
ACVR1 NM_001105.4
ACVR1B NM_020328.3
AKT1 NM_001014432.1+
AKT2 NM_001626.4+
AKT3 NM_005465.4
ALK NM_004304.4^+
ANKRD11 NM_001256182.1
ANKRD26 NM_014915.2
APC NM_000038.5+
AR NM_000044.3+
ARAF NM_001654.4
ARFRP1 NM_003224.4
ARID1A NM_006015.4
ARID1B NM_020732.3
ARID2 NM_152641.2
ARID5B NM_032199.2
ASXL1 NM_015338.5
ASXL2 NM_018263.4
ATM NM_000051.3+
ATR NM_001184.3
ATRX NM_000489.3+
AURKA NM_198433.1
AURKB NM_004217.3
AXIN1 NM_003502.3
AXIN2 NM_004655.3
AXL NM_021913.4
B2M NM_004048.2
BAP1 NM_004656.3
BARD1 NM_000465.2
BBC3 NM_001127240.2
BCL10 NM_003921.4
BCL2 NM_000633.2
BCL2L1 NM_138578.1
BCL2L11 NM_001204108.1
BCL2L2 NM_001199839.1
DNAJB1 NM_006145.1
DNMT1 NM_001130823.1
DNMT3A NM_022552.4
DNMT3B NM_006892.3
DOT1L NM_032482.2
E2F3 NM_001949.4
EED NM_003797.3
EGFL7 NM_016215.4
EGFR NM_005228.3^+
EIF1AX NM_001412.3
EIF4A2 NM_001967.3
EIF4E NM_001130679.1
EML4 NM_019063.3
EP300 NM_001429.3
EPCAM NM_002354.2
EPHA3 NM_005233.5
EPHA5 NM_004439.5
EPHA7 NM_004440.3
EPHB1 NM_004441.4
ERBB2 NM_004448.2+
ERBB3 NM_001982.3+
ERBB4 NM_005235.2
ERCC1 NM_001983.3+
ERCC2 NM_000400.3+
ERCC3 NM_000122.1
ERCC4 NM_005236.2
ERCC5 NM_000123.3
ERG NM_001136154.1
ERRFI1 NM_018948.3
ESR1 NM_001122742.1+
ETS1 NM_001143820.1
ETV1 NM_004956.4^
ETV4 NM_001079675.2^
ETV5 NM_004454.2
ETV6 NM_001987.4^
EWSR1 NM_013986.3^
H2BC5 NM_021063.3
H3C1 NM_003529.2
H3C2 NM_003537.3
H3C3 NM_003531.2+
H3C4 NM_003530.4
H3C6 NM_003532.2
H3C7 NM_021018.2
H3C8 NM_003534.2
H3C10 NM_003536.2
H3C11 NM_003533.2
H3C12 NM_003535.2
H3C15 NM_001005464.2
H3C14 NM_021059.2
H3C13 NM_001123375.2
H3-4 NM_003493.2
HLA-A NM_002116.7
HLA-B NM_005514.6
HLA-C NM_002117.5
HNF1A NM_000545.5
HNRNPK NM_002140.3
HOXB13 NM_006361.5
HRAS NM_005343.2+
HSD3B1 NM_000862.2
HSP90AA1 NM_001017963.2
ICOSLG NM_015259.4
ID3 NM_002167.4
IDH1 NM_005896.2+
IDH2 NM_002168.2+
IGF1 NM_001111283.1
IGF1R NM_000875.3
IGF2 NM_001127598.1
IKBKE NM_014002.3
IKZF1 NM_006060.4
IL10 NM_000572.2
IL7R NM_002185.3
INHA NM_002191.3
INHBA NM_002192.2
INPP4A NM_001134224.1
INPP4B NM_003866.2
MYC NM_002467.4+
MYCL NM_001033082.2+
MYCN NM_005378.4+
MYD88 NM_002468.4+
MYOD1 NM_002478.4
NAB2 NM_005967.3^
NBN NM_002485.4
NCOA3 NM_181659.2
NCOR1 NM_006311.3
NEGR1 NM_173808.2
NF1 NM_001042492.2+
NF2 NM_000268.3+
NFE2L2 NM_006164.4+
NFKBIA NM_020529.2
NKX2-1 NM_001079668.2
NKX3-1 NM_006167.3
NOTCH1 NM_017617.3
NOTCH2 NM_024408.3
NOTCH3 NM_000435.2
NOTCH4 NM_004557.3
NPM1 NM_002520.6
NRAS NM_002524.4+
NRG1 NM_013964.3+
NSD1 NM_022455.4
NTRK1 NM_002529.3^
NTRK2 NM_006180.3^
NTRK3 NM_001012338.2
NUP93 NM_014669.4
NUTM1 NM_175741.1^
PAK1 NM_001128620.1
PAK3 NM_002578.3
PAK5 NM_020341.3
PALB2 NM_024675.3
PRKN NM_004562.2
PARP1 NM_001618.3
COP1 NM_022457.5
RHEB NM_005614.3
RHOA NM_001664.2
RICTOR NM_152756.3+
RIT1 NM_006912.5
RNF43 NM_017763.4
ROS1 NM_002944.2^
RPS6KA4 NM_003942.2
RPS6KB1 NM_003161.3+
RPS6KB2 NM_003952.2
RPTOR NM_020761.2
RUNX1 NM_001754.4
RUNX1T1 NM_175635.2
RYBP NM_012234.5
SDHA NM_004168.2
SDHAF2 NM_017841.2
SDHB NM_003000.2
SDHC NM_003001.3
SDHD NM_003002.3
SETBP1 NM_015559.2
SETD2 NM_014159.6+
SF3B1 NM_012433.2
SH2B3 NM_005475.2
SH2D1A NM_002351.4
SHQ1 NM_018130.2
SLIT2 NM_004787.1
SLX4 NM_032444.2
SMAD2 NM_005901.5
SMAD3 NM_005902.3
SMAD4 NM_005359.5+
SMARCA4 NM_001128849.1+
SMARCB1 NM_003073.3+
SMARCD1 NM_003076.4
SMC1A NM_006306.3
SMC3 NM_005445.3
SMO NM_005631.4+
SNCAIP NM_005460.2

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BELAY DIAGNOSTICS

Date: 11/10/2026
Order ID: SumAsc-Pos-Breast-ERBB2

1375 W. Fulton Street, Suite 530
Chicago, IL 60607
Email: contact@belaydiagnostics.com
Phone: (331) 320-0155 | Fax: (800) 501-9246

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BCL6 NM_001706.4
BCOR NM_001123385.1
BCORL1 NM_021946.4
BCR NM_004327.3^
BIRC3 NM_001165.4
BLM NM_000057.2
BMPR1A NM_004329.2
BRAF NM_004333.4^+
BRCA1 NM_007294.3+
BRCA2 NM_000059.3+
BRD4 NM_058243.2
BRIP1 NM_032043.2
BTG1 NM_001731.2
BTK NM_000061.2
EMSY NM_020193.3
CALR NM_004343.3
CARD11 NM_032415.4
CASP8 NM_001228.4
CBFB NM_001755.2
CBL NM_005188.3
CCND1 NM_053056.2+
CCND2 NM_001759.3
CCND3 NM_001760.3+
CCNE1 NM_001238.2+
CD274 NM_014143.3
CD276 NM_001024736.1
CD74 NM_001025159.2^
CD79A NM_001783.3
CD79B NM_000626.2+
CDC73 NM_024529.4
CDH1 NM_004360.3+
CDK12 NM_016507.2
CDK4 NM_000075.3+
CDK6 NM_001259.6+
CDK8 NM_001260.1
CDKN1A NM_000389.4
CDKN1B NM_004064.3
CDKN2A NM_000077.4+
CDKN2B NM_004936.3+
CDKN2C NM_001262.2
CEBPA NM_004364.3
CENPA NM_001809.3
CHD2 NM_001271.3
CHD4 NM_001273.2
CHEK1 NM_001114122.2+
CHEK2 NM_007194.3+
CIC NM_015125.3+
CREBBP NM_004380.2
CRKL NM_005207.3
CRLF2 NM_022148.2
CSF1R NM_005211.3
CSF3R NM_156039.3
CSNK1A1 NM_001025105.2
CTCF NM_006565.3
CTLA4 NM_005214.4
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CTNNB1 NM_001904.3+
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CXCR4 NM_003467.2
EZH2 NM_004456.4
AMER1 NM_152424.3
ABRAXAS1 NM_139076.2
TENT5C NM_017709.3
FANCA NM_000135.2
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FANCF NM_022725.3
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FGFR4 NM_213647.1+
FH NM_000143.3
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FOXO1 NM_002015.3
FOXP1 NM_032682.5
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FYN NM_002037.5
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GID4 NM_024052.4
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GNAQ NM_002072.3
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JUN NM_002228.3
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MDC1 NM_014641.2
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MEN1 NM_130799.2
MET NM_000245.2+
MGA NM_001164273.1
MITF NM_000248.3
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MSH6 NM_000179.2
MST1 NM_020998.3
MST1R NM_002447.2
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PAX7 NM_001135254.1
PAX8 NM_013953.3^
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PDCD1 NM_005018.2
PDCD1LG2 NM_025239.3
PDGFRA NM_006206.4+
PDGFRB NM_002609.3+
PDK1 NM_001278549.1
PDPK1 NM_002613.4
PGR NM_000926.4
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RAC1 NM_018890.3
RAD21 NM_006265.2
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RAD52 NM_134424.2
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RAF1 NM_002880.3+
RANBP2 NM_006267.4
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SOX9 NM_000346.3
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SPTA1 NM_003126.2
SRC NM_198291.2
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STAG2 NM_001042749.1
STAT3 NM_139276.2
STAT4 NM_003151.3
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STAT5B NM_012448.3
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STK40 NM_032017.1
SUFU NM_016169.3+
SUZ12 NM_015355.2
SYK NM_003177.5
TBX3 NM_016569.3
ELOC NM_005648.3
TCF3 NM_003200.3
TCF7L2 NM_030756.4
TERC
TERT NM_198253.2+
TET1 NM_030625.2
TET2 NM_001127208.2
TFE3 NM_006521.4^
TFRC NM_003234.2+
TGFBR1 NM_004612.2
TGFBR2 NM_001024847.2
TMEM127 NM_017849.3
TMPRSS2 NM_001135099.1^
TNFAIP3 NM_006290.3
TNFRSF14 NM_003820.2
TOP1 NM_003286.2
TOP2A NM_001067.3
TP53 NM_000546.5+
TP63 NM_003722.4
TRAF2 NM_021138.3
TRAF7 NM_032271.2+
TSC1 NM_000368.4
TSC2 NM_000548.3
TSHR NM_000369.2
U2AF1 NM_006758.2
VEGFA NM_001025366.2
VHL NM_000551.3+
VTCN1 NM_024626.3
CCN6 NM_003880.3
WT1 NM_024426.4
XIAP NM_001167.3
XPO1 NM_003400.3
XRCC2 NM_005431.1
YAP1 NM_001130145.2
YES1 NM_005433.3
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ZBTB7A NM_015898.2
ZFHX3 NM_006885.3
ZNF217 NM_006526.2
ZNF703 NM_025069.1
ZRSR2 NM_005089.3
MTAP NM_002451.3+*

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1375 W. Fulton Street, Suite 530
Chicago, IL 60607
Email: contact@belaydiagnostics.com
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CYLD NM_015247.2	*GPS2* NM_004489.4	*MUTYH* NM_001128425.1	*RARA* NM_000964.3	
DAXX NM_001141970.1	*GREM1* NM_013372.6	*MYB* NM_001130173.1	*RASA1* NM_002890.2	
DCUN1D1 NM_020640.2	*GRIN2A* NM_000833.3		*RB1* NM_000321.2+	
DDR2 NM_001014796.1	*GRM3* NM_000840.2		*RBM10* NM_005676.4	
DDX41 NM_016222.2	*GSK3B* NM_002093.3		*RECQL4* NM_004260.3	
DHX15 NM_001358.2	*H3-3A* NM_002107.4+		*REL* NM_002908.2	
DICER1 NM_177438.2	*H3-3B* NM_005324.3		*RET* NM_020975.4^+	
DIS3 NM_014953.3	*H3-5* NM_001013699.2			
	HGF NM_000601.4			
	H1-2 NM_005319.3			

^Summit™ also reports fusion events for this gene
+Summit™ also reports copy number alterations for this gene
*Summit™ only reports copy number alterations for this gene

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

The Summit™ 2.0 comprehensive genomic profiling (CGP) next-generation sequencing (NGS) test investigates tumor derived nucleic acid extracted from cerebrospinal fluid (CSF) for clinically relevant single/multi nucleotide variants (SNVs, MNVs), insertions and deletions (indels), gene level copy number variants (CNVs), and other biomarkers such as tumor mutation burden (TMB) and microsatellite instability (MSI). Methodology involves evaluation of 520 genes for SNVs, MNVs, Indels, 62 genes for CNVs, 28 genes for fusions, as well as TMB and MSI (PMID: 41595175). The LOD (limit of detection) for SNVs, MNVs and Indels was determined to be 0.3% variant allelic frequency (VAF), for CNVs was determined to be >=2-fold change for amplifications and <=0.5-fold change for deletions, and for fusions was determined to be >=2 supporting reads. Reporting thresholds for TMB and MSI are: <10 Mut/Mb (TMB low), >=10 Mut/Mb (TMB high), and when total unstable sites are <30% (MSS) and >=30% (MSI-High). 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 log2(*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 1.5.0, 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.

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

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1375 W. Fulton Street, Suite 530
Chicago, IL 60607
Email: contact@belaydiagnostics.com
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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)

NCCN: National Comprehensive Cancer Network® (NCCN®). Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. The NCCN Guidelines® and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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

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