Client Update

BioReference® | GenPath®

April 2023

Test Name	Test Code	Effective Date
OnkoSight Advanced™ NGS Breast Cancer Panel	TP57-6	Immediately

The Cancer Genomics department of BioReference®/GenPath® is pleased to launch **OnkoSight Advanced next-generation sequencing (NGS) panel for Breast Cancer.**

Molecular testing for genetic and genomic variation has become a standard of care for many types of malignancies and is becoming increasingly important in the management of advanced breast cancer. With next-generation sequencing, multiple genes can be tested simultaneously, saving time for patients who may be waiting for these results prior to making treatment decisions.[1]

- Commonly acquired mutations in breast cancer include those in the ER (ESR1) associated with resistance to aromatase inhibitors in ER+ advanced breast cancers, and genes in the MAP kinase pathway such as NF1, KRAS, and NRAS genes.
- Targetable mutations in advanced breast cancer include PIK3CA, HER2, and rare instances of mismatch deficiency or other targets for tyrosine kinase inhibitors.
- Tumor somatic testing may identify patients for clinical trial eligibility and investigation of precision medicine approaches to advanced breast cancer.

Please reach out to your dedicated account executive for any questions.

Test Information	
Primary Container	BLK - Formalin-fixed, Paraffin-embedded Tissue
Minimum Volume	40 ng DNA (Required)
Turn Around Time*	~4-10 days
Transportation Temp	Specimen can be either RT or refrigerated. Ship with cold pack during warm weather.
Methodology	Next-Generation Sequencing (NGS)
Collection Instructions	BLK: This comes in block form from client with surgical number imprint
Profile Components	AKT1, AR, ATM, ATR, ATRX, BARD1, BRAF, BRCA1, BRCA2, BRIP1, CCNE1, CDH1, CDK12, CHEK1, CHEK2, EGFR, EPCAM, ERBB2, ERBB3, ERBB4, ESR1, FANCA, FANCC, FANCL, FGFR1, FGFR2, FOXA1, KRAS, MLH1, MRE11A, MSH2, MSH6, MUTYH, MYC, NBN, PALB2, PIK3CA, PMS2, PTEN, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD54L, RB1, RECQL4, TERT, TP53, XRCC2
CPT Code(s)**	81445x1

Reference:

1. *Jennifer K. Litto et a., Molecular Testing in Breast Cancer American Society of Clinical Oncology Educational Book 2019:39, e1-e7*

FLT3 by PCR	TP13-9	Immediately

BioReference®/GenPath® now offers **FLT3 mutational analysis by PCR for Internal tandem duplications (ITD) and exon 20 tyrosine kinase domain (TKD)**. FLT3 mutation can help with risk stratification in Acute Myeloid Leukemia (AML) and has therapeutic utility as a potential target for inhibitor therapy.

Test Information	
Primary Container	LPB Lavender Top
Minimum Volume	2mL
Turn Around Time*	~3 days
Transportation Temp	Specimen can be either RT or refrigerated. Ship with cold pack during warm weather.
Stability	14 days
Methodology	Polymerase Chain Reaction (PCR)
Collection Instructions	LPB: Fill tube, invert gently 5-6 times, label with patient's name
CPT Code(s)**	81245x1; 81246x1

** TAT is based upon receipt of the specimen at the laboratory.*
***CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.*
****Healthcare providers should only order panels if each test in the panel is medically necessary.*

481 Edward H. Ross Drive, Elmwood Park, NJ 07407 | tel 800.229.5227 | fax 201.791.1941 | www.bioreference.com

Client Update

BioReference® | GenPath®

Test Name	Test Code	Effective Date
Arsenic, Blood	J019	March 15, 2023

The reference range for **Arsenic, Blood** (Test Code J019) has been updated. Please see below for details:

	Previous Test Information	New Test Information
Reference Range	2-23 ug/L	<24 ug/L

Test Name	Test Code	Effective Date
Epi proColon®, Septin 9 Gene Methylation Detection, IVD	A515	Immediately

Due to a change in performing reference laboratories, some test information for **Epi proColon, Septin 9 Gene Methylation Detection, IVD** (Test Code A515) has been updated. Please see below for details:

Test Information	
Turn Around Time*	12 days
Transportation Temp	Strict Frozen
Collection Instructions	Please label each final plasma collection tube with the word "Plasma". Testing will be delayed if the tube is not labeled properly. *Blood Collection:* • Blood should be collected according to your laboratory's procedure for venipuncture using only a 4-mL BD® purple-top (K_2 EDTA) tube. Plasma preparation should be performed within four hours after blood is collected. Store, transport, and ship plasma at frozen condition only. The plasma sample can be stored frozen at -15°C to -25°C for 14 days. • Do not freeze whole blood samples. *Plasma Specimen Preparation:* • Immediately following specimen collection, label all tubes with appropriate patient information (two patient identifiers, minimum). • Centrifuge the six BD purple-top (K_2 EDTA) tubes for 10 minutes at 1600±90 rcf. (For conversion of RPM [revolutions per minute] to rcf [relative centrifugal force], refer to the centrifuge manufacturer's user manual.) • Remove blood collection tubes from the centrifuge. (Plasma sample will be rejected if it is hemolyzed. Patient will be contacted.) • Using a fresh, six-inch disposable transfer pipette, transfer plasma from three 4-mL tubes to one 8.5-mL Sarstedt centrifuge tube (55.598.006). • Repeat this process with the second set of three 4-mL tubes. Two 8.5-mL tubes will be collected from six 4-mL tubes. • Centrifuge plasma in the 8.5-mL centrifuge tube for 10 minutes at 1600±90 rcf. • Using a fresh, six-inch disposable transfer pipette or serological pipette, transfer 3.5 mL of plasma from one 8.5-mL centrifuge tube into a labeled 7-mL Sarstedt screw-cap, flat-bottom purple frozen transport tube (62.550.019). • Repeat this process with the second 8.5-mL centrifuge tube. • Two 7-mL tubes will be collected. • Ship and store plasma at -15°C to -25°C. Stable for 14 days. • Take care not to disturb or transfer the buffy coat (white blood cells) layered above the red blood cells in the blood collection tube after the first centrifugation or sedimented at the bottom of the centrifuge tube after the second centrifugation.
CPT Code(s)**	81327

Test Name	Test Code	Effective Date
Matrix Metalloproteinase-9	B792	March 17, 2023

Due to changes at the performing reference laboratory, the transport temperature for **Matrix Metalloproteinase-9** (Test Code B792) has been revised. Please see below for details:

	Previous Test Information	New Test Information
Transportation Temperature	Frozen	Strict Frozen

Test Name	Test Code	Effective Date
Vitamin B12	0160	March 23, 2023

Due to changes in instrumentation at the Elmwood Park, NJ laboratory, the reference range for **Vitamin B12** (Test Code 0160) testing has been revised. Please see below for details:

	Previous Test Information	New Test Information
Reference Range	211-911 pg/mL	232-1245 pg/mL

Test Name	Test Code	Effective Date
REGIONAL UPDATE: INR	1112	April 3, 2023

Due to a new reagent lot number, the reference range for **Protime/INR** (Test Code 1112) has been updated, when performed at our Melbourne, FL laboratory location. Please see below for details:

	Previous Test Information	New Test Information
Reference Range	0.81-1.16	0.84-1.21

** TAT is based upon receipt of the specimen at the laboratory.*
***CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.*
****Healthcare providers should only order panels if each test in the panel is medically necessary.*

481 Edward H. Ross Drive, Elmwood Park, NJ 07407 | tel 800.229.5227 | fax 201.791.1941 | www.bioreference.com