Client Update

BioReference® | GenPath®

Test Name	Test Code	Effective Date
ClariTest® Core Non-Invasive Prenatal Screening	**TH18-5 and TH19-3**	**March 1, 2023**

Due to changes in the internal claims processes implemented by many insurance companies, BioReference® and GenPath® Women's Health are implementing an update to clinical information before ordering **Claritest® Core NIPS** (Test Codes TH18-5 and TH19-3). Effective March 1, 2023, NIPS orders will require the following questions be answered upon order entry:

Patient received pretest counseling regarding screening options from:

- Physician
- Board certified genetic counselor
- Other healthcare professional
- Unknown

Please note that for clients that have non-global EMR compendiums, the client will need to open a ticket with their EMR vendor and add the additional AOE questions manually.

ClariTest® Core Non-Invasive Prenatal Screening	**TH18-5 and TH19-3**	**March 1, 2023**

As part of the BioReference and GenPath Women's Health ongoing HIPAA-compliant quality assurance program, and in accordance with several state Department of Health directives, we will be requesting pregnancy outcome information for patients who had NIPS performed at BioReference. The pregnancy outcome data will be de-identified and used in full compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations.

Pregnancy outcome data is a valuable part of any NIPS program. It allows BioReference and GenPath to assess the sensitivity and specificity of our test and provide your patients with the most accurate test results possible. We know your time is valuable and we appreciate any follow-up information you can provide.

Beginning the last week of April, pregnancy outcome request forms will be emailed or faxed to clients for all high risk and unreportable NIPS results and a small portion of low risk results. Your dedicated account executive will be reaching out soon to confirm your preferred method of receiving outcome requests.

Glomerular Filtration Rate (GFR or e-GFR)	**Multiple**	**March 1, 2023**

Based on recommendation standards by the National Kidney Foundation, BioReference will adopt the new **CKD-EPI Creatinine equation (2021)**, effective March 1, 2023.

Glomerular filtration rate (GFR or e-GFR) is the best overall index of renal function. GFR varies with age, sex, and body size, and declines with age. This new equation, for the same creatinine value, will estimate a lower GFR for Black patients and a higher GFR for non-Black patients.

Neopterin	**TN21-6**	**Immediately**

Please be advised that due to changes at the performing reference laboratory, specimen stability requirements have been updated for **Neopterin** (Test Code TN21-6**)**. Please see below for details:

Previous Specimen Stability	New Specimen Stability
Refrigerated: 7 Days Frozen: 180 Days	Refrigerated: 3 Days Frozen: 180 Days

**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

Test Name	Test Code	Effective Date
OnkoSight Advanced™ 523 Gene NGS Reanalysis	**TM56-4**	**Immediately**

The Cancer Genomics department of BioReference® and GenPath® Oncology is pleased to launch **OnkoSight Advanced™ 523 Gene NGS Reanalysis (Test Code TM56-4).**

OnkoSight Advanced, a DNA-based next-generation sequencing (NGS) test from GenPath, will allow reanalysis of previously established sequencing data using up-to-date guidelines, and new variant-disease associations. At GenPath we take a guideline-driven approach in the design of our panels but we also understand that in certain circumstances clinicians need to look beyond guidelines for therapy options. Reanalysis solves that very problem and enables clinicians to initially use a smaller, targeted panel to treat their patients and then, if required, have over 500 genes reanalyzed without the need for re-sequencing.

OnkoSight Advanced Reanalysis will not require new sample submission or sequencing. All OnkoSight Advanced NGS panels listed below are eligible for the Reanalysis Report:

TP51 – OnkoSight Advanced Bladder Cancer Panel	TH48 – OnkoSight Advanced Prostate Cancer Panel
TH57 – OnkoSight Advanced CNS Panel	TJ16 – OnkoSight Advanced Solid Tumor Panel
TH50 – OnkoSight Advanced Colorectal Cancer Panel	TJ93 – OnkoSight Advanced Chronic Lymphoid Neoplasm Panel (FFPE)
TH58 – OnkoSight Advanced Gastrointestinal Stromal Tumor Panel	TH55 – OnkoSight Advanced Chronic Lymphoid Neoplasm Panel (PB/BM)
TH53 – OnkoSight Advanced GYN Tumor Panel	TL68 – OnkoSight Advanced Multiple Myeloma (FFPE)
TH49 – OnkoSight Advanced Lung Cancer Panel	TL67 – OnkoSight Advanced Multiple Myeloma (PB/BM)
TH59 – OnkoSight Advanced Melanoma Panel	
TK84 – OnkoSight Advanced Pancreaticobiliary Panel	

Additional test details can be found in the table below. Please reach out to your dedicated Account Executive or call Customer Service if you have any questions about this announcement. To view the gene components of panels eligible for reanalysis, please visit our online test directory https://www.genpathdiagnostics.com/test-directory/?search=OnkoSight+Advanced

	Test Information
Test Name	OnkoSight AdvancedTM 523 Gene NGS Reanalysis
Test Code	TM56-4
CPT Code(s)**	81479

-CONTINUED ON NEXT PAGE-

**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.*

Test Name	Test Code	Effective Date
OnkoSight Advanced™ Comprehensive Lung Panel	**M338-2**	
OnkoSight Advanced™ Comprehensive CNS Panel	**M339-0**	**Immediately**
OnkoSight Advanced™ Comprehensive Thyroid Panel	**M340-8**	

The Cancer Genomics department of BioReference® and GenPath® Oncology is pleased to offer **OnkoSight Advanced™ Comprehensive NGS profiles for lung, central nervous system (CNS), and thyroid cancers**. These were designed to help with ease of ordering. The NGS profiles combine DNA and RNA panels, and genomic biomarkers (e.g., TMB, MSI, and/or PD-L1) for prognosis and treatment management.

Profile components and other test details can be found in the table below. Please reach out to your dedicated Account Executive or call Customer Service if you have any questions about this announcement.

	Test Information		
Test Name	Comprehensive Lung Panel	Comprehensive CNS Panel	Comprehensive Thyroid Panel
Test Code	M338-2	M339-0	M340-8
Panel Components	• DNA – OnkoSight Advanced Lung Panel- 22 genes, TMB, and MSI (Test code TH49-0) • RNA - Solid Tumor Gene Fusion Panel- 18 genes (Test code J355-9) • PD-L1 22C3 by IHC (Test code B993-7)	• DNA – OnkoSight Advanced CNS Panel- 29 genes, TMB, and MSI (Test code TH57-3) • RNA – Solid Tumor Gene Fusion Panel- 18 genes (Test code J355-9)	• DNA – OnkoSight Advanced Solid Tumor Panel- 50 genes, TMB, and MSI (Test code TJ16-5) • RNA – Solid Tumor Gene Fusion Panel – 18 genes (Test code J355-9)
CPT Code(s)**	CPT code(s): 81455x1, 81449x1, 88360x1	CPT code(s): 81445x1, 81449x1	CPT code(s): 81445x1, 81449x1

-CONTINUED ON NEXT PAGE-

**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.*

Test Name	Test Code	Effective Date
OnkoSight Advanced™ NGS Bladder Cancer Panel	**TP51-9**	**Immediately**

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

Genetic alterations are common in bladder cancer. Data from the Cancer Genome Atlas ranks bladder cancer as the third most commonly mutated cancer.[1] Treatment options for bladder cancer are dependent on the stage of the disease and other factors and may include chemotherapy, immunotherapy, and targeted therapy among others. National guidelines recommend that molecular/genomic testing be performed at diagnosis for stages IVA and IVB bladder cancer, and may be considered for stage IIIB to:[1]

- Facilitate treatment decision-making and eligibility for FDA-approved therapies
- Prevent delays in administering later lines of therapy
- Screen for clinical trial eligibility

Test details can be found in the table below. Please reach out to your dedicated Account Executive or call Customer Service if you have any questions about this announcement.

	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	ARID1A, ATM, BRAF, BRCA2, CCND1, CCNE1, CDKN2A, CREBBP, EGFR, EP300, ERBB2, ERBB3, ERCC2, FANCA, FBXW7, FGFR1, FGFR2, FGFR3, HRAS, KDM6A, KMT2A, KMT2C, KMT2D, KRAS, LRP1B, MAP2K1, MDM2, NF1, NRAS, PIK3CA, PRKDC, PTEN, RB1, SMARCA4, SPEN, STAG2, TERT, TP53, TSC1
CPT Code(s)**	81445x1

References:

1. *NCCN® Clinical Practice Guidelines in Oncology Bladder Cancer Version 3.2022. Accessed 1.9.2023*

-CONTINUED ON NEXT PAGE-

**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.*

Test Name	Test Code	Effective Date
T-cell Gene Rearrangement by NGS	**TN50-5**	**IMMEDIATELY**

The Cancer Genomics and Molecular Pathology department of BioReference® and GenPath® Oncology is pleased to inform you that we are transitioning our **T-cell gene rearrangement testing from polymerase chain reaction (PCR) to next-generation sequencing (NGS)**.

T-cell lymphomas (TCL) account for less than 10% of all cases of non-Hodgkin lymphomas, but they represent the most aggressive lymphoid tumors.[1]

- TCR gene rearrangement is indicative of T-cell clonal expansion. The test targets the gamma and/or beta TCR genes using PCR methods with capillary or gel electrophoresis detection methods.[2] However, only 80% of TCL are found to show a PCR-detectable clone. Additionally, some clonal lymphocyte populations may also appear in non-neoplastic situations such as infections, immunodeficiency, and autoimmune disorders.[1]
- Next-generation sequencing (NGS)-based clonality assessment allows for broader molecular profiling of tumors, which has generated extensive additional information relevant to both malignancy and tumor classification.[1]

There will be no changes to specimen requirements. Please reach out to your dedicated Account Executive or call Customer Service if you have any questions about this announcement.

References:

1. *Syrykh C, Gorez P, Grand D, et.al., Molecular diagnosis of T-cell lymphoma: A correlative study of PCR-based T-cell clonality assessment and targeted NGS.*
2. *NCCN Clinical Practice Guidelines in Oncology T-Cell Lymphomas Version 2.2022- March 7, 2022.*

-END-

**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