Client Update

BioReference LABORATORIES | genpath
OPKO Health Companies

MARCH 2021

Test Name	Test Code	Effective Date
C-Telopeptide	**T421-7**	**February 15, 2021**

Per an in-house study, reference range for **C-Telopeptide** has been updated. Please refer to the table below.

	Previous Test Information	New Test Information
Reference Range	Postmenopausal 104-1008 pg/mL	Postmenopausal 49 – 738 pg/mL

Culture, Genital- Beta strep. Group B (Penicillin Allergic) **A265-1** **February 17, 2021**

In an effort to remove duplicate test codes, please be advised that effective immediately, **Culture, Genital-Beta strep. Group B (Test Code A265)** will no longer be available to order. The alternative suggested test is **Culture, Genital- Beta strep. Group B (Test Code 3400),** which offers the same components as A265. If A265 is ordered, 3400 will automatically be performed.

	Previous Test Information	Alternate Test Information
Primary Container	Swab- E	Swab- E
Turn Around Time*	4 days	4 days
Collection Instructions	Collect specimen with swab then place swab into transport carrier; Label with name and source	Collect specimen with swab then place swab into transport carrier; Label with name and source
CPT Code(s)**	87070	87070

Hemoglobin Fractionation, HPLC **0216-2** **March 7, 2021**

Due to validation on a new analytical platform, reference ranges for **Hemoglobin Fractionations** have been updated. Please refer to the table below.

	Previous Test Information	New Test Information
Methodology	Trinity Biotech HPLC	Sebia Capillarys
Reference Range	Age Dependent Reference Range	Non-Age Dependent Reference Range

Variants	Birth to 3 mo	3 mo – 1 year	1 yr – 2 years	Above 2 years
Hb A	15.0 - 50.0 %	85.0 – 100.0 %	95.0 – 100.0 %	96.0 – 99.0%
Hb A2	0.0 – 1.0 %	2.0 – 3.5 %	2.0 – 3.5 %	1.5 – 3.7 %
Hb F	50.0 – 85.0 %	Up to 15.0 %	Up to 5.0 %	0.0 – 2.0 %
Hb S	Not Detected	Not Detected	Not Detected	Not Detected
Hb C	Not Detected	Not Detected	Not Detected	Not Detected
Hb Other	Not Detected	Not Detected	Not Detected	Not Detected

-Hemoglobin A: 96.7-97.8 %
-Hemoglobin F: ≤ 0.5 %
-Hemoglobin A2: 2.2-3.2 %

Lavender Top Specimen **N/A** **Immediately**

Please be advised that when a lavender cap specimen tube is received with no test ordered, CBC (Test code 0053) will presumptively be performed due to the limited stability of the specimen. If you want to receive the CBC results, please contact 1-800-229-5227 Option #1 to have the test added.

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Test Name	Test Code	Effective Date
OnkoSight Advanced Chronic Lymphoid NGS Panel (Tissue Only) – 31 genes, TMB and MSI	**TJ93-4**	**March 1, 2021**

OnkoSight Advanced Chronic Lymphoid NGS Panel (Tissue Only) – 31 genes, TMB and MSI is now available for order. This test is equal in genetic analysis to GenPath's OnkoSight Advanced Chronic Lymphoid Neoplasm NGS Panel (Test Code TH55-7). This updated version is designated to accommodate formalin-fixed, paraffin-embedded (FFPE) tissue. Tissue specimens can be used to detect potentially actionable mutations that are directly relevant to routine clinical laboratory evaluation of Chronic Lymphocytic Leukemia/Small lymphocytic lymphoma (CLL/SLL), Lymphoplasmacytic lymphoma (LPL)/Waldenstrom Macroglobulinema, T-cell lymphomas including T-cell large granular lymphocytic leukemia (T-LGLL), and Diffuse Large B-cell Lymphomas, among others. Please find test information below.

	New Test Information
Primary Container	BLK – Formalin-fixed, Paraffin-embedded Tissue
Minimum Volume	15 unstained slides at 5 microns (tumor content>10%) with H&E, Shavings (if tumor content>40%) with H&E. If sending DNA- Please call Client Services.
Turn Around Time*	5-10 days
Transportation Temp	Specimen can be either RT or refrigerated Ship with cold pack during warm weather
Methodology	Genotyping by Next-Generation Sequencing
Collection Instructions	This comes in block form from client with surgical number imprint
Profile Components	ATM, BCL2, BCL6, BIRC3, BRAF, BTK, CARD11, CD79B, CDKN2A, CXCR4, DNMT3A, EZH2, IDH1, IDH2, JAK, JAK1, KMT2D, MAP2K1, MYD88, NOTCH1, NOTCH2, NRAS, PLCG2, RHOA, SETD2, SF3B1, STAT3, STAT5B, TET2, TNFRSF14, TP53
CPT Code(s)**	81445x1, 88381x1
List Price	$2000

Test Name	Test Code	Effective Date
OnkoSight Advanced Comprehensive Lung Panel	**TK78-2**	**March 1, 2021**

OnkoSight Advanced Comprehensive Lung Panel is now available for order. Clinical sequencing of tumor DNA has received clinical attention with an emphasis on detection of hotspot single nucleotide variants (SNVs), small insertions and deletions (INDELs), and copy number variants (CNVs) that confer sensitivity to targeted therapies. Gene fusions (detected by RNA) have emerged as an important class of markers for precision medicine in solid tumors. GenPath offers targeted RNA analysis by NGS with distinct advantages over IHC and FISH in relation to sensitivity, specificity, and multiplexing density. This test combines those two NGS testing possibilities into a single orderable for non-small cell lung cancer (NSCLC). Please find test information below.

	New Test Information
Primary Container	BLK - Formalin-fixed, Paraffin-embedded Tissue
Minimum Volume	30 unstained slides at 10 microns (tumor content>10%) with H&E, Shavings (if tumor content>40%) with H&E. Extracted DNA and TNA are acceptable, provided that the isolation of nucleic acid occurs in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS and/or the CAP.
Turn Around Time*	10 days
Transportation Temp	Ship with cold pack during warm weather. Total Nucleic Acid (TNA) must shipped on dry ice
Methodology	Genotyping by Next-Generation Sequencing
Collection Instructions	This comes in block form from client with surgical number imprint.
Profile Components	TH49 OnkoSight Advanced Lung Cancer NGS Panel - 18 genes (AKT1, ALK, BRAF, DDR2, EGFR, ERBB2, FGFR1, KRAS, MAP2K1, MET, NRAS, NTRK1, PIK3CA, POLD1, POLE, STK11, TERT, TP53, TSC1, TSC2, TP53, VHL), TMB, and MSI J355 Solid Tumor Gene Fusion Assay - 18 genes (ALK, AXL, BRAF, CCND1, EGFR, FGFR1, FGFR2, FGFR3, MET, NRG1, NTRK1, NTRK2, NTRK3, PPARG, RAF1, RET, ROS1, THADA)
CPT Code(s)**	**81445x1, 88381x1**
List Price	$2500.00

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Test Name	Test Code	Effective Date
OnkoSight Advanced Pancreatic and Biliary Tract Tumor Panel (21 genes, TMB, and MSI)	**TK84-0**	**March 1, 2021**

OnkoSight Advanced Pancreatic and Biliary Tract Tumor Panel (21 genes, TMB, and MSI) is now available for order. Per NCCN Clinical Guideline recommendations for Pancreatic Adenocarcinoma, Tumor/Somatic gene profiling is recommended for patients with locally advanced/metastatic disease who are candidates for anti-cancer therapy to identify uncommon mutations. Consider specifically testing for actionable somatic findings including, but not limited to: fusions (ALK, NRG1, NTRK, ROS1), mutations (BRAF, BRCA1/2, HER2, KRAS, PALB2), and mismatch repair (MMR) deficiency (detected by tumor IHC, PCR, or NGS). Please find test information below.

Reference: NCCN Guidelines Version 1.2021 Pancreatic Adenocarcinoma

	New Test Information
Primary Container	BLK - Formalin-fixed, Paraffin-embedded Tissue
Minimum Volume	15 unstained slides at 5 microns (tumor content>10%) with H&E, Shavings (if tumor content>40%) with H&E. If sending DNA- Please call Client Services.
Turn Around Time*	5-10 days
Transportation Temp	Specimen can be either RT or refrigerated Ship with cold pack during warm weather
Methodology	Genotyping by Next-generation Sequencing
Collection Instructions	This comes in block form from client with surgical number imprint
Profile Components	ARID1A, BRAF, BRCA1, BRCA2, ERBB2, FGFR1, FGFR2, FGFR3, IDH1, IDH2, KRAS, MLH1, MSH2, MSH6, NRAS, PALB2, PIK3C2G, PMS2, STK11, TGFBR2, TP53
CPT Code(s)**	81445x1, 88381x1
List Price	$2000

OnkoSight Advanced Prostate Cancer Panel (28 genes, TMB, and MSI) **TH48-2** **March 1, 2021**

The Cancer Genomics Department constantly evaluates the gene content of OnkoSight Advanced NGS panels. Effective March 1st, the **OnkoSight Advanced Prostate Cancer Panel** will additionally include the following genes: *BARD1, BRIP1, CDK12, CHEK1, FANCL, RAD51B, RAD51C, RAD54L, RB1, PPP2R2A*, and *TP53*. NCCN Guidelines recommend the evaluation of homologous recombination genes (HHR) for genomic instability caused by mutations in genes involved in the repair of double-stranded DNA breaks known as homologous recombination deficiency (HRD). This update combined with the current gene content addresses the best-known genes in the repair complex. Further, this update adds-in evaluation for defects in genes with HRD that are susceptible to platinum-based chemotherapy. This update does not change the CPT coding or any established pricing. Please find test information below.

Reference: NCCN Guidelines Version 2.2021 Prostate Cancer

	Previous Test Information	New Test Information
Profile Components	AR, ATM, BRCA1, BRCA2, CHEK2, EPCAM, FAN-CA, HOXB13, MLH1, MSH2, MSH6, NTRK1, PALB2, PMS2, PTEN, RAD51D, TERT	AR, ATM, BARD1, BRCA1, BRCA2, BRIP1, CDK12, CHEK1, CHEK2, EPCAM, FANCA, FANCL, HOXB13, MLH1, MSH2, MSH6, NTRK1, PALB, PMS2, PPP2R2A, PTEN, RAD51B, RAD51C, RAD51D, RAD54L, RB1, TERT, TP53

Pathologist Review, Peripheral Smear **5106-0** **April 1, 2021**

The test code for a **Pathologist Review, Peripheral Smear** will be retired. As an alternative, please use **CBC with Differential (Test Code 0053-9)**. The CBC with Differential will provide an assessment of white blood cells, the count with differential, red cell counts and indices, and platelet count. The collection instructions for 0053-0 are the same as for the retiring 5106-0.

Please find test information on next page.

Test Name	Test Code	Effective Date

	New Test Information
Primary Container	Lavender-top (EDTA) tube
Minimum Volume	1 mL
Turn Around Time*	1 day
Transportation Temp	Refrigerated
Methodology	Flow cytometry
Collection Instructions	Invert 8-10 times. DO NOT SHAKE TUBE!
Profile Components	HCT, WBC, RBC, HGB, PLATELET COUNT
CPT Code(s)**	85025
List Price	$30

PD-L1 22C3 for Keytruda for Triple-Negative Breast Cancer TL02-0 March 1, 2021

PD-L1 22C3 for Keytruda for Triple-Negative Breast Cancer is now available for order. PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using monoclonal mouse anti-PD-L1. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying Triple-negative Breast Cancer (TNBC) patients who are eligible for treatment with KEYTRUDA® (pembrolizumab). PD-L1 protein expression in TNBC is determined by using the Combined Positive Score (CPS) which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS>=10. Please find test information below.

	New Test Information
Primary Container	BLK- Formalin-fixed, Paraffin-embedded Tissue
Turn Around Time*	1 day
Transportation Temp	This comes in block form from client with surgical number imprint. Storage/Transport Instruction: Ship with cold pack during warm weather.
Stability	
Methodology	Immunohistochemistry (IHC)
Collection Instructions	This comes in block form from client with surgical number imprint
CPT Code(s)**	88360x1
List Price	$475

Plasma 10-color Myeloma/Monoclonal Gammopathy Panel TK97-2 - With Interpretation March 1, 2021
TK96-4 – Tech Only

The flow cytometry laboratory is pleased to add plasma cell testing to the 10-color flow cytometry offering effective March 1. As previously announced in December 2020 the flow cytometry laboratory started to convert to 10-color flow cytometry, with the initial launch including the Acute and Chronic flow cytometry panels.

The **new 10-color flow cytometry panel for plasma cell neoplasms and monoclonal gammopathy** offers several potential advantages over prior 6-color panel. These include the following:

- Simultaneous detection of clonal plasma cells and clonal B-cells without need for additional panels (e.g., chronic panel) to identify clonal B-cells and precisely define their phenotype (e.g., CD5 or CD10 expression).
- Increased accuracy of population identification.
    - The use of greater numbers of informative antibodies results in a geometric increase in the informational content of the data generated making this methodology more sensitive in identification abnormal population.
- Making better use of small specimens.
- Decreasing the number of additional flow tests (“add-ons”).

- Continued on next page -

Test Name	Test Code	Effective Date

The 6-Color plasma cell panels will remain available during the transition and eventually withdrawn as a conclusion to the transition (date to be determined). Please work with your GenPath Commercial representative on this transition; established client pricing will not change.

- Plasma Cell Analysis (Myeloma) – Global (Test Code 5573-1)
- Plasma Cell Analysis (Myeloma)- Tech Only (Test Code 5574-9)

Please note Plasma Cell Analysis (Myeloma) Tech Only (Test Code 5574-9) will remain orderable for Reverse-TC clients.

Please find test information below.

	New Test Information
Primary Container	BMG- Bone Marrow- Green Top
Minimum Volume	If submitting Peripheral Blood Lav, 5 ml is required
Turn Around Time*	1 day
Transportation Temp	Room Temperature
Methodology	Flow Cytometry
Profile Components	CD5, CD10, CD19, CD20, CD23, CD27, CD33, CD38, CD45, CD56, CD81, CD117, CD200, Kappa, Lambda, IgA, IgG, IgM
CPT Code(s)**	88184x1, 88185x21, 88189x1 (With Interp) 88184x1, 88185x21 (Tech Only)
List Price	$4,450 (with Interp) $3,300 (Tech Only)
Clinical Utility (If applicable)	Monoclonal gammopathy, increased plasma cells, lytic bone lesions

T3, Free **0271-7** **February 1, 2021**

Per an in-house study, reference range for **T3, Free** has been updated. Please refer to the table below.

	Previous Test Information	New Test Information
Reference Range	T3, FREE(FT3) REFERENCE RANGE Age Range (pg/mL) 0-30 days 1.7-5.4 2-23 mo 1.1-6.3 2-5 yrs 2.5-5.5 6-10 yrs 3.0-5.4 11-14 yrs 2.8-5.2 15-18 yrs 2.5-4.7 >18 yrs 2.0-4.7	T3, FREE(FT3) REFERENCE RANGE Age Range (pg/mL) 0-30 days 1.7-5.4 31-60 days Not Established 2-23 mo 3.7-5.6 2-5 yrs 3.2-5.8 6-10 yrs 2.8-5.4 11-14 yrs 3.2-5.2 15-18 yrs 2.7-4.6 >18 yrs 2.1-3.9

T3, Total **0150-3** **February 2, 2021**

Per an in-house study, reference range for **T3, Total** has been updated. Please refer to the table below.

	Previous Test Information	New Test Information
Reference Range	T3(THYRONINE), TOTAL REFERENCE RANGE Age Range (ng/dL) 0-30 days 75-205 2-23 mo 65-260 2-5 yrs 103-236 6-10 yrs 114-222 11-14 yrs 105-211 15-18 yrs 89-191 >18 yrs 72-180	T3(THYRONINE), TOTAL REFERENCE RANGE Age Range (ng/dL) 0-30 days 75-205 31-60 days Not Established 2-23 mo 112-245 2-5 yrs 124-221 6-10 yrs 115-219 11-14 yrs 103-216 15-18 yrs 87-179 >18 yrs 69-154

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Test Name	Test Code	Effective Date
Thyroxine, Free (FT4)	**0091-9**	**January 27, 2021**

Per an in-house study, reference range for **Thyroxine, Free (FT4)** has been updated. Please refer to the table below.

	Previous Test Information	New Test Information
Reference Range	THYROXINE, FREE (FT4) REFERENCE RANGE Age Range (ng/dL) 0-30 days 0.81-2.01 2-23 mo 0.87-1.83 2-5 yrs 0.98-1.66 6-10 yrs 0.97-1.61 11-14 yrs 0.86-1.53 15-18 yrs 0.86-1.58 >18 yrs 0.80-1.73	THYROXINE, FREE (FT4) REFERENCE RANGE Age Range (ng/dL) 0-30 days 0.99-3.02 31-60 days Not Established 2-23 mo 1.00-1.70 2-5 yrs 1.04-1.64 6-10 yrs 1.01-1.58 11-14 yrs 0.88-1.52 15-18 yrs 0.92-1.61 >18 yrs 0.84-1.62

T4 (Thyroxine) Total **0151-1** **January 28, 2021**

Per an in-house study, reference range for **T4 (Thyroxine) Total** has been updated. Please refer to the table below.

	Previous Test Information	New Test Information
Reference Range	THYROXINE, TOTAL (T4) REFERENCE RANGE Age Range (ug/dL) 0-30 days 4.5-14.4 2-23 mo 4.5-14.0 2-5 yrs 5.8-12.5 6-10 yrs 5.7-11.9 11-14 yrs 4.8-11.3 15-18 yrs 4.7-11.6 >18 yrs 4.9-12.9	THYROXINE, TOTAL (T4) REFERENCE RANGE Age Range (ug/dL) 0-30 days 5.9-19.4 31-60 days Not Established 2-23 mo 5.9-12.6 2-5 yrs 6.1-11.2 6-10 yrs 5.9-10.6 11-14 yrs 5.4-10.0 15-18 yrs 5.3-10.1 >18 yrs 4.9-10.6

** 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.*

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