Client Update

BioReference® | GenPath®

May and June 2023

Test Name	Test Code	Effective Date
AAMI Water Analysis	1795-4	May 19. 2023

Specimen requirements and transport media for **AAMI Water Analysis (Test Code 1795)** have been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Primary Container	CUP – Cup Plain	OTH – Other (forced comment)
Minimum Volume	10 mL	25mL
Stability	7 days	14 days
Collection Instructions	Place sample in sterile cup label with patient's name and source.	Use Trace Water Bottle (100 mL) certified for trace element analysis provided by Spectra, or dialysate bag.

ClariTest® Core Non Invasive Prenatal Screening **TH18-5 and TH19-3** **July 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 July 1, 2023, NIPS orders will require the following questions be provided upon order entry:

Clinical indications

- Routine Screening
- Advanced Maternal Age
- Abnormal Antenatal Screen for: _____
- Family History: _____
- Ultrasound Finding(s):_____
- Previous Pregnancy History: _____

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 Ask on Order Entry (AOE) questions manually.

CT/GC/Trich **Multiple** **May 31, 2023**

Please be advised that effective May 31, 2023, the reference range interval for the tests listed below will change from "Negative" to "Not Detected". The result choices will be now be Detected, Not Detected, Inconclusive, Invalid, or Unable to Amplify result. The test codes, CPT codes, list price, and collection types will remain the same.

Additionally, test code A861- Trichomonas Vaginalis, Probe rRNA will now require a "Specimen Source" AOE to be answered.

Test Code	Test Name
A111	Gonorrhea, Oral Aptima
A113	Chlamydia, Oral Aptima
A112	Gonorrhea, Anal Aptima
A114	Chlamydia, Anal Aptima
6368	Chlamydia Trachomatis, Urine, rRNA
6369	Gonorrhea, urine, rrna
1004	Chlamydia, swab, TMA, Aptima
1003	Gonorrhea, rRNA, TMA Aptima Swab
A861	Trichomonas Vaginalis, Probe rRNA

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****Healthcare providers should only order panels if each test in the panel is medically necessary.*

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Test Name	Test Code	Effective Date
FOLR1 by IHC	TP73-3 Global TP74-1 Tech Only	Immediately

We are pleased to offer **FOLR1 by IHC (Test Code TP73)**, the FDA-approved companion diagnostic test for determining folate receptor 1 protein (FOLR1), also known as folate receptor alpha (FRa) expression in epithelial ovarian-type cancers (ovary, fallopian tube, primary peritoneal sites), for patients who may benefit from ELAHERE (mirvetuximab soravtansine). The overexpression of FOLR1 is often associated with increased cancer progression and poor patient prognosis.

Please refer to the table below for test details.

	New Test Information
Primary Container	BLK - Formalin-fixed, Paraffin-embedded Tissue
Turn Around Time*	~3 days
Transportation Temp	Room Temperature; Ship block with cold pack during warm weather
Methodology	Immunohistochemistry
Collection Instructions	BLK: This comes in block form from client with surgical number imprint
CPT Code(s)**	88360x1

Please visit www.fda.com to view full prescribing information on ELAHERE.

Hepatitis B Surface Antigen, Quant.	1608-9	April 30, 2023

Due to a change in test platform and methodology, **Hepatitis B surface Antigen (Test Code 1608)** will no longer be performed at our laboratory. **Hepatitis B Surface Antigen (Test Code 0106)** will be used to replace with the new methodology. Please note that no index value will be listed on the report.

We also offer **Quantitative hepatitis B virus RT-PCR DNA testing (Test Code 3389),** to monitor patients with a confirmed diagnosis of Hepatitis B Virus infection and inform treatment decisions.

Lead, Blood Adult and Child	1438-1 and 0398-8	May 4, 2023

Reference range for **Lead, Blood Adult and Child (Test Code 1438 and 0398)** has been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Reference Range	<5.0 µg /dL	Adult/Children ≥ 6 years: <5.0 µg /dL Children <6 years: <3.5 µg /dL

Pathology Requisitions	Multiple	Immediately

Please be reminded when sending **surgical pathology requisitions**, ICD-10 codes, site of specimen and relevant clinical history needs to be indicated.

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Test Name	Test Code	Effective Date
OnkoSight Advanced™ Pan Heme Fusion NGS Panel (73 genes)	TP02-2	Immediately

We are pleased to now offer OnkoSight Advanced Pan Heme Fusion Panel by next-generation sequencing (NGS) for hematologic malignancies (Test Code TP02).

Fusions arise due to genomic rearrangements that include chromosomal inversion, interstitial deletions, duplications, and translocations. Conventional methodologies such as chromosome analysis, fluorescence in situ hybridization (FISH), and RT-PCR have been used to detect gene rearrangements, but these procedures have limitations (e.g., t(12;21)(p13;q22) with ETV6-RUNX1 is often missed in the analysis of chromosomes, and translocations that involve KMT2A (MLL), which has >100 partner genes with numerous different breakpoints, are not fully covered by the limited number of primer sets used in RT-PCR).

- A clinical study of 7000 tumors from The Cancer Genome Atlas Project found 3% of tumors contained a likely oncogenic kinase fusion. In hematological malignancies, higher frequencies of fusions are found in acute myelogenous leukemia (20% of patients); acute lymphoblastic leukemia (30%); B-cell neoplasms (30%); T-cell neoplasms (15%), and chronic myelogenous leukemia (100%).

OnkoSight Advanced™ Pan Heme Fusion NGS Panel is an orderable non-compendium test. Please refer to the test details below, and speak to your Account Executive if you want to order this test.

	New Test Information
Primary Container	BLK - Formalin-fixed, Paraffin-embedded Tissue
Turn Around Time*	~7-10 days
Transportation Temp	Specimen can be sent either room temperature or refrigerated; Ship with cold pack during warm weather
Methodology	Next-generation Sequencing
Collection Instructions	BML/BMG: Place bone marrow into tube, label with patient's name and date of birth. GPB/LPB: Place peripheral blood into tube, label with patient's name and date of birth. If submitting Bone Marrow or Peripheral Blood, 5 ml is required. BLK: This comes in block form from client with surgical number imprint. Custom Instruction: 10-15 unstained slides at 5 microns (tumor content>10%) with H&E, stable for 30 days. Alternative specimen: Extracted Total Nucleic Acid (TNA) or RNA is acceptable, providing 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.
Gene Components	ABL1, ABL2, ALK, BCL11B, BCL2, BCL6, BCR, BIRC3, CBFB, CCND1, CCND3, CDK6, CHD1, CHIC2, CIITA, CREBBP, CRLF2, CSF1R, DEK, DUSP22, EBF1, EIF4A1, EPOR, ERG, ETV6, FGFR1,GLIS2, IKZF1, IKZF2, IKZF3, JAK2, KAT6A, KLF2, KMT2A, MALT1, MECOM, MKL1, MLF1, MLLT10, MLLT4, MYC, MYH11, NF1, NFKB2, NOTCH1, NTRK3, NUP214, NUP98, P2RY8, PAG1, PAX5, PBX1, PDCD1L G2, PDGFRA, PDGFRB, PICALM, PML, PRDM16, PTK2B, RARA, RBM15, ROS1, RUNX1, RUNX1T1, SEMA6A, SETD2, STIL, TAL1, TCF3, TFG, TP63, TYK2, ZCCHC7
CPT Code(s)**	81455x1

References:
1. Nikanjam M, Okamura R, Barkauskas DA, Kurzrock R. Targeting fusions for improved outcomes in oncology treatment. Cancer. 2020 Mar 15;126(6):1315-1321. doi: 10.1002/cncr.32649. Epub 2019 Dec 3. PMID: 31794076; PMCID: PMC7050395.
2. Borahm Kim, Hyeonah Lee, Saeam Shin, Seung-Tae Lee, Jong Rak Choi, Clinical Evaluation of Massively Parallel RNA Sequencing for Detecting Recurrent Gene Fusions in Hematologic Malignancies, The Journal of Molecular Diagnostics, Volume 21, Issue 1, 2019.

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Test Name	Test Code	Effective Date
Prenatal CMV IgG/IgM with reflex to CMV IgG Avidity when IgG is positive	M351-5	May 1, 2023

We are pleased to now offer **Prenatal CMV IgG/IgM with reflex to CMV IgG Avidity when IgG is positive (Test Code M351)**.

According to the Centers for Disease Control and Prevention (CDC), Cytomegalovirus (CMV) is the most common infectious cause of birth defects in the United States. This new reflex test code simplifies the ordering process by providing the information needed to assess a patient's risk of having a baby with congenital CMV with a single blood draw. CMV Ab. IgG and CMV IgM are first performed and if IgG is positive, CMV IgG Avidity will reflex.

Please refer to the test details below for more information.

	New Test Information
Primary Container	Serum Separator Tube
Minimum Volume	1 ml
Transportation Temp	Refrigerate
Stability	7 days
Methodology	CMV Ab. IgG- Chemiluminescence Enzyme Linked Immunoabsorbance
Collection Instructions	SST: Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hour, spin for 10-15 minutes
Profile Components	CMV Ab. IgG, CMV IgM, reflex to CMV Avidity, IgG
CPT Code(s)**	86644, 86645 87332 (if test reflexes)
List Price	$190.10 plus $112.00 if reflex is performed

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