Client Update

BioReference LABORATORIES | genpath | LABORATORIO Buena Salud

OPKO Health Companies

MARCH 2019

Test Name	Test Code	Effective Date
Other – ICD-10 Code Search Tool	**N/A**	**Immediately**

We are pleased to announce a new tool to help providers easily search for appropriate ICD-10 codes. This tool provides educational information regarding Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) for certain laboratory services. To access this search function, visit https://www.bioreference.com/physicians/resources/icd10-search/

Note: Any 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. The provision of this information as a customer service does not suggest and is not meant to suggest that any code should or should not be used on any given occasion. BioReference makes no recommendation regarding the use of any particular diagnosis code(s). Diagnosis information should be reflected in the patient's medical record.

Other - Insurance Coverage	**N/A**	**Immediately**

BioReference Laboratories is pleased to continue to be an in-network provider with most national health plans and hundreds of regional plans, including:

- United Healthcare
- Aetna
- Cigna
- Anthem
- Medicare & Medicaid

While some national plans have made changes in their network, these changes DO NOT AFFECT BioReference and its specialty labs, GenPath and GeneDx. BioReference looks forward to providing you and your patients with quality diagnostic services throughout 2019.

For a complete list of health plans contracted with BioReference, please visit www.bioreference.com

Alprazolam + Metabolite, Urine	**3864**	**February 25**

Due to changes at our reference laboratory, test information for **Alprazolam + Metabolite, Urine** has been updated. Please refer to table below for changes.

	Previous Test Information	New Test Information
Specimen Requirements	Urine – Sterile Container	Urine – Sterile Container
Minimum Volume	2 mL	1 mL
Turn Around Time*	7 days	8 days
Stability	Ambient – N/A Refrig – 7 days Frozen – N/A	Ambient – 14 days Refrig – 30 days Frozen – 30 days
Reference Range	<50ng/mL	NONE DETECTED
Profile Components	Alprazolam Hydroxyalprazolam	Alpha-Hydroxyalprazolam Alprazolam

ALT	**A913**	**Immediately**

Due to use of new reagent, reference ranges for **ALT** have been updated. Please refer to table below for changes.

	Previous Test Information	New Test Information
Reference Range	• Male 21-72 U/L • Female 9-52 U/L	• Male <50 U/L • Female <35 U/L

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Test Name	Test Code	Effective Date
Anti-DsDNA	**0364**	**March 18**
Anti-SSB	**0868**	
Anti-Smith	**0851**	
Centromere Autoabs	**0587**	
Anti-RNP	**0852**	
SCL-70	**0315**	
Anti-SSA (Anti-Ro52, Anti-Ro60)	**0853**	

BioReference Laboratories will begin using the **INOVA BioFlash analyzer** for the detection of the following **secondary ANA antibodies: DsDNA, SM, RNP, Centromere, Scl70, SSB, SSA Ro52 and SSA Ro60**. This analyzer uses chemiluminescent technology. It offers improved analytical sensitivity, specificity and wide linear ranges.

With the introduction of this new instrument, the SM/RNP antibody test will be replaced by RNP. In addition, the two types of Anti-Ro (SS-A 52) and Anti-Ro (SSA-60) will be reported. The distinction between the two types of SSA antibodies will further facilitate the diagnosis of several connective diseases such as Systemic Lupus Erythematosus, Sjogren's syndrome, Systemic sclerosis (SSc), Mixed Connective Tissue Disease and idiopathic inflammatory myopathies often with overlapping clinical presentation.

While SS-A 52 is mostly present together with SS-A 60 in patients with Systemic Lupus (SLE) and Sjogren's syndrome (SS), high frequency of isolated Anti-SSA-52 has been seen in systemic sclerosis (SSc), and idiopathic inflammatory myopathies.

Reference ranges for **Anti-DsDNA** are as follows:

	Previous Test Information	New Test Information
Methodology	Bioplex Multiplex	BioFlash Chemiluminescence
Reference Range	• < or=4 IU/mL: Negative • 5-9 IU/mL: Borderline Positive • > or=10 IU/mL: Positive	• <27.0 IU/mL: Negative • 27.0-35.0 IU/mL: Indeterminate • >35.0 IU/mL: Positive

Reference ranges for other listed **Secondary ANA Antibodies** are as follows:

	Previous Test Information	New Test Information
Methodology	Bioplex Multiplex	BioFlash Chemiluminescence
Reference Range	• <1.0 AI	• <20.0 CU

Bile Acids Fractionated	**3917**	**March 18**
Bile Acids, Fract. + Total Pregnancy	**J676**	

The reference laboratory that completes testing for **Bile Acids Fractionated** has added the following comments to result reports:

- For test code 3917 - Bile Acids Fractionated:
  For pregnant patients: please order test code J676 - Bile Acids, Fract. + Total Pregnancy

- For test code J676 - Bile Acids, Fract. + Total Pregnancy:
  For non-pregnant patients: please order test code 3917 - Bile Acids Fractionated

Test Name	Test Code	Effective Date
BRAF and EGFR by NGS, if EGFR negative reflex to ALK1 by FISH, if negative reflex to ROS1 by FISH	**TB34 (Global Only)**	**March 4**

As previously announced, we are now pleased to offer **BRAF and EGFR by NGS with reflex to ALK and ROS1 by FISH.**

KRAS assesses for resistance to anti-EGFR therapy in metastatic colorectal cancer and TKI therapy resistance in lung cancer. BRAF V600E/K mutation analysis is useful in the context of melanoma, colorectal cancer, thyroid cancer, and hairy cell leukemia. Melanoma patients with V600E/K mutations are eligible for treatment with TKI inhibitor therapy. In colorectal cancer, BRAF may be used as a screening assay for MSI-H or unstable patients suspected of Lynch Syndrome. BRAF V600E can aid in the diagnosis of papillary thyroid cancer (PTC) from cytology samples. Numerous studies have shown BRAF to be associated with aggressive clinic-pathologic features of PTC. BRAF can also be used to confirm a diagnosis of Hairy Cell Leukemia.

	Test Information
Specimen Requirements	Formalin-fixed Paraffin-embedded Tissue
Turn Around Time*	10 days
Transportation Temperature	Room Temperature
Methodology	Next-Generation Sequencing (NGS), Fluorescent In-Situ Hybridization (FISH)
Collection Instructions	This comes in block from client with surgical number imprint
CPT Code(s)**	81210x1, 81235x1

Cryofibrinogen	**3908**	**Immediately**

Due to changes at our reference laboratory, test information for **Cryofibrinogen** has been updated. Please refer to table below for changes.

	Previous Test Information	**New Test Information**
Specimen Requirements	1 (Red Top) and 1 (ALQE)	Plasma (Light Blue Top or Lavender Top)
Minimum Volume	2mL	3mL
Turn Around Time*	13 days	8 days
Collection Instructions	Serum: The specimen must be allowed to clot at 37° C immediately after being drawn. After clotting, the serum is quickly separated from the clot, preferably using preheated carriers in the centrifuge. Lipemic and non-fasting specimens cannot be accepted. Plasma: The EDTA tube is drawn and kept at 37° C. The plasma is quickly separated from the whole blood by spinning in preheated carriers. Do not refrigerate or freeze. Storage/Transport Instruction: AMBIENT	Collect blood in (light blue-top) or (lavender-top) tubes. Place immediately in a 37° C water bath. Centrifuge blood specimens in centrifuge carriers prewarmed to 37° C at 3000 rpm for a minimum of 10 minutes. Separate plasma from red cells, avoiding transfer of red cells, into plastic transport tubes.
Profile Components	Cryofibrinogen Cryoglobulin, Qualitative	Cryofibrinogen
CPT Code(s)**	82585, 82595	82585

Test Name	Test Code	Effective Date
MUC4 by IHC	**TF92 (Tech Only)** **TF93 (Global)**	**March 6**

GenPath Oncology is pleased now offer **MUC4 by IHC** for Pancreatic Carcinoma and Low-grade Fibromyxoid Sarcoma.

Pancreatic ductal adenocarcinoma (PDA) comprises 85% of all pancreatic malignancies and morphologically may resemble autoimmune pancreatitis. Pancreatic cancer has a poor prognosis, whereas autoimmune pancreatitis is a benign mimic that is treatable.

- MUC4 has been published as having 77% sensitivity and 78% specificity in the differentiation of PDA from Chronic Pancreatitis[1]

Additionally, MUC4 has clinical utility in soft tissue tumor diagnosis as it is highly sensitive and specific for low-grade fibromyxoid sarcoma (LGFMS). MUC4 differentiates LGFMS from soft tissue mimics.

- In one study, MUC4 stained 100% of LGFMS but stained none of soft tissue perineuriomas, myxofibrosarcomas, cellular myxomas, solitary fibrous tumors, low-grade malignant peripheral nerve sheath tumors, desmoid fibromatosis, neurofibromas, schwannomas, dermatofibrosarcoma, protuberans, myxoid liposarcomas, and extraskeletal myxoid chrondrosarcomas[2]

	Test Information
Specimen Requirements	BLK – Formalin-fixed, Paraffin-embedded Tissue
Turn Around Time*	1 day
Transportation Temperature	Room temperature
Methodology	Immunohistochemistry
Collection Instructions	This comes in block from client with surgical number imprint
CPT Code(s)**	88342

References:

1. Arch Pathol Lab Med 2007;131:556-62
2. Am J Surg Pathol. 2011; 35:733-41

Test Name	Test Code	Effective Date
Sulfide Exposure Bio-Uptake Marker, Serum/Plasma	**3901**	**Immediately**

Due to changes at our reference laboratory, test information for **Sulfide Exposure Bio-Uptake Marker, Serum/Plasma** has been updated. Please refer to table below for changes.

	Previous Test Information	New Test Information
Specimen Requirements	Serum (SST or Red Top) or Plasma (Green Top)	Serum (Red Top) or Plasma (all acceptable except Green Top and Lavender Top)
Minimum Volume	3mL	2mL
Methodology	Chromatography	Liquid chromatography–mass spectrometry

NOTES:

Client updates are also available to be received via email instead of fax. To subscribe to receive client updates via email, please visit http://bit.ly/BRLIGoGreen

** TAT is based upon receipt of the specimen at the laboratory*

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